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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 02/JUNE/2009

Subject: Methoxyfenozide. Registrant's Response to Conditional Registrations for Uses and/or Tolerances on Leaf Vegetables, Rotational Crops, Stone Fruits, and Poultry Commodities. Summary of Analytical Chemistry and Residue Data.

PC Code: 121027
Decision No.: 359469, 332799, 333780
Petition No.: 9F06062, 0F06201, 0F06213, 1F06259
Risk Assessment Type: None
TXR No.: None
MRID No.: 46606301, 45870501, 45870502, 46039301

DP Barcode: 322948, 288924, 295721, 295680
Registration No.: 62719-442
Regulatory Action: Conditional Data Review

Case No.: NA
CAS No.: 161050-58-4
40 CFR: 180.544

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I. CONCLUSIONS

Regulatory Recommendations

The submitted data/information adequately resolve the deficiencies pertaining (1) multiresidue method testing data for metabolites; (2) residues of RH-141,518 in poultry meat and fat; (3) spinach and plum field trials; and (4) rotational crop field trials. However, additional residue data are still required on celery and mustard greens (see below).

The available spinach residue data indicate that the current tolerance for leafy greens, subgroup 4A is adequate; however, the plum field trial data indicate that the tolerance for plums should be increased to 0.6 ppm. Based on established tolerances for primary crops and the available residue data on the representative rotational crops (turnips, onions, wheat and soybeans), the tolerances for inadvertent or indirect residues of methoxyfenozide should be amended as follows (See also Table 9.):

> Based on the available turnip residue data, the tolerance for root and tuber vegetables (crop group 1) should be changed to tuberous and corm vegetables (subgroup 1C) and reduced to 0.05 ppm. Based on the onion residue data, the tolerance for bulb vegetables (crop group 3) should be reduced to 0.1 ppm. Based on the soybean residue data, the tolerance for legume vegetables (crop group 6) should be changed to pea and bean, dried and shelled, except soybean (subgroup 6C) and increased to 1.0 ppm. The soybean seed data also supports establishing a new tolerance for combined residues in oil seeds (crop group 20) at 1.0 ppm. Based on the wheat data, the tolerances for cereal grain forage, fodder and straw (crop group 16) and grass forage, fodder and hay (crop group 17) should both be lowered to 6.0 ppm. Based on the wheat forage and hay residue data, the tolerance for herbs and spices (group 19) should be lowered to 4.5 ppm. Based on the soybean forage and hay data, the tolerance for nongrass animal feeds (crop group 18) should be lowered to 8.0 ppm.

Residue Chemistry Deficiencies

860.1500 Crop Field Trials

- Additional field trials are required on celery and mustard greens supporting the registered use pattern (DP# 260888, M. Nelson, 07/AUG/2002). Two celery field trials are required in EPA growing Region 3, and three mustard green field trials are required, one each in EPA growing Regions 2, 3, and 10.

860.1550 Proposed Tolerances

- A summary of recommended tolerances along with recommendations to commodity definition are presented in Table 9. The petitioner should submit a revised Section F, pertaining to petition numbers: PP#0F06201, PP#1F06259, PP# 9F06062 and PP# 0F06213 to amend commodity definitions and the established tolerances in 1) 40 CFR §180.544 (a)(1) in/on plum, prune, fresh from 0.3 ppm to 0.6 ppm; 2) 40 CFR §180.544 (d)(1) in/on vegetable, bulb, group 3, vegetable, root and tuber, group 1, and vegetable,

root and tuber, leaves, group 2 from 0.20 ppm, 0.10 ppm and 0.20 ppm, respectively to 0.10 ppm, 0.05 ppm, and deleted, respectively; 3) 40 CFR §180.544 (d)(2) in/on vegetable, legume, group 6 from 0.1 ppm to 1.0 ppm, vegetable, foliage of legume, group 7 should be deleted, grain, cereal, forage fodder and straw, group 16 from 10.0 ppm to 6.0 ppm, grass, forage, fodder and hay, group 17 from 10.0 ppm to 6.0 ppm, animal feed, nongrass, group 18 from 10.0 ppm to 8.0 ppm, herband spice, group 19 from 10.0 ppm to 4.5 ppm and oil seed, group 20 to 1.0 ppm as shown in Table 9.

II. ACTION REQUESTED

Dow AgroSciences has submitted for review multiresidue method testing data on the metabolites, spinach and plum field trial data, rotational crop field trial data, and a waiver request for the additional poultry residue data in response to the following Agency conditional registration requirements (DP# 259549, M. Nelson, 07/AUG/2002).

- Submission of multiresidue method testing data for metabolites RH-141,518, RH-117,236, RH-151,055, and RH-152,072.
- Submission of additional field trials on spinach (3 trials), celery (2 trials), mustard greens (3 trials) and plums (2 trials) at the labeled use rate.
- Submission of the residue data for metabolite RH-141,518 in fat and muscle from the poultry feeding study, along with supporting storage stability data, and revise poultry tolerances as necessary.
- Submission of additional field accumulation trials in rotational crops.

III. EXECUTIVE SUMMARY

Methoxyfenozide (benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazine) is a diacylhydrazine insecticide used on a wide variety of food and feed crops for the control of lepidopterous pest species. A 22.6% flowable concentrate (2 lb/gal FlC) and a 80% wettable powder (WP) are registered to Dow AgroSciences for use as repeated foliar applications to field, vegetable, fruit, and tree nut crops using ground or aerial equipment at rates of 0.06-0.25 lb ai/A/application, for maximum seasonal rates of 0.75-1.0 lb ai/A. The labeled preharvest intervals (PHIs) range from 1 to 30 days.

Permanent tolerances are established for residues of methoxyfenozide *per se* in/on a wide variety of plant commodities at levels ranging from 0.05 ppm in/on field corn grain and sweet corn ears to 160 ppm in/on soybean aspirated grain fractions [40 CFR §180.544(a)(1)]. Permanent tolerances are also established for residues of methoxyfenozide *per se* in milk, meat, fat of livestock [40 CFR §180.544(a)(1)], and for the combined residues of parent and its glucuronide conjugate (RH-141,518) in eggs and meat byproducts at 0.02-0.40 ppm [40 CFR §180.544(a)(2)]. Tolerances have also been established for inadvertent or indirect residues of methoxyfenozide *per se* in high-moisture rotational crops and for the combined residues of methoxyfenozide, its phenol metabolite (RH-117,236), and its glucoysl conjugates (RH-151,055 and RH-152,072) in low-moisture rotational crops [40 CFR §180.544(d)(1 and 2)].

As a condition of registration for methoxyfenozide on a variety of crops, the Agency requested additional data pertaining to: (1) multiresidue method testing data for the regulated metabolites; (2) residue data for Metabolite RH-141,518 in poultry meat and fat; (3) additional crop field trials on spinach, celery, mustard greens and plums; and (4) extensive rotational crop field trials. In response to the above requirements, Dow AgroSciences has submitted multiresidue method testing data on the metabolites, spinach and plum field trials, rotational crop field trials, and a waiver request for the additional poultry residue data. No new tolerances have been requested for plant or animal commodities. The adequacy of the submitted data is evaluated in this report, along with their impact on the current tolerances.

Based on the acceptable metabolism studies on cotton, apples, grapes, and rice and the confined rotational crop study, the nature of methoxyfenozide residues in primary and rotational crops is adequately understood. The HED Metabolism Assessment Review Committee (MARC) concluded that the residue of concern for both the tolerance expression and the risk assessment in primary crops (and drinking water) is methoxyfenozide *per se*. For rotational crops, the MARC concluded that the residues of concern for purposes of tolerance enforcement include only the parent compound in high-moisture rotational crops and the combined residues of parent, RH-117,236, RH-151,055 and RH-152,072 in low-moisture rotational crops. For risk assessment purposes, the metabolites RH-152,067, RH-131,157 and RH-152,071 will also be taken into account in rotational crops.

The qualitative nature of methoxyfenozide residues in livestock is also adequately understood based on available ruminant and poultry metabolism studies. The MARC determined that the residue of concern is parent in milk and ruminant tissues (except meat byproducts), poultry meat and fat. The residues of concern in ruminant meat byproducts, eggs and poultry meat byproducts include methoxyfenozide and Metabolite RH-141,518.

Adequate high performance liquid chromatography with ultra violet or mass spectrometry (HPLC/UV or MS) detection methods are available for enforcing the current tolerances of methoxyfenozide on primary crops, rotational crops and animal commodities. Depending on the plant commodity, the limit of quantitation (LOQ) for methoxyfenozide in primary crop commodities is 0.01-0.05 ppm. In rotational crops, the LOQs are 0.02 ppm each for methoxyfenozide and RH-117,236, and 0.05 ppm for RH-151,055 (which includes RH-152,072). When expressed in parent equivalents, the LOQ for combined residues in rotational crops is 0.077 ppm. In the submitted spinach, plum and rotational crop field trials, residues of methoxyfenozide and its metabolites were determined using either the approved enforcement methods (spinach and rotational crops) or a liquid chromatography with tandem mass spectrometry (LC/MS/MS) method (plums). Each data collection method was adequately validated in conjunction with the analysis of spinach field trial samples.

Adequate multiresidue method testing data are now available for parent and its regulated metabolites. Based on these data, the FDA multiresidue methods are not suitable for analysis of methoxyfenozide and its regulated metabolites.

Adequate cattle and poultry feeding studies are available. Based on the calculated maximum dietary burden (MDB) for poultry (0.94 ppm) and the information provided from the poultry feeding and metabolism studies, residues for RH-141,518 are not likely to be detectable in

poultry meat and fat at dosing levels up to 25x MDB. Therefore, analysis of poultry meat and fat samples for residues of RH-141,518 are not required. The available feeding studies support the current tolerances on livestock commodities.

The submitted spinach and plum field trial data are adequate. The additional field trials were conducted at 1x – 1.8x the maximum labeled use rate and samples were harvested at the appropriate PHIs. Together with the data from previously submitted spinach and plum field trials, the new data were used to assess the current tolerances on leafy greens (subgroup 4A) and plums, fresh prunes. The data indicate that the current tolerance for leafy greens at 30 ppm is adequate, but the current tolerance on plums at 0.3 ppm should be increased to 0.6 ppm.

The submitted rotational crop field trials are adequate and support the labeled 7-day plant-back interval (PBI) for rotational crops without registered uses. Although the required number of field trials was not conducted for each representative crop, the field trials were all conducted at 2x the maximum seasonal use rate on field and vegetable crops. Therefore, the residue data will serve as a conservative estimate of residues in rotational crops. In addition, rotational crop residue data are no longer required on numerous commodities, as tolerances have been established on a wide variety of primary crops, crop groups, and subgroups. Considering both the limited and extensive field trials, a total of 14 rotational crop field trials are available reflecting the application of methoxyfenozide at a seasonal rate of 2 lb ai/A (2x rate). These rotational crop field trials include residue data on turnips (6 trials), wheat (8 trials), soybeans (8 trials), and onions (3 trials). The residue data on the commodities from these representative crops are adequate for assessing rotational crop tolerances on the following crop groups or subgroups: tuberous and corm vegetables (subgroup 1C); bulb vegetables (crop group 3); dried shelled peas and beans, except soybean (subgroup 6C); forage, fodder and straw of cereal grains (crop group 16); grass forage, fodder and hay (crop group 17); nongrass animal feeds (crop group 18); herbs and spices (crop group 19); and oil seeds (crop group 20).

Background

Methoxyfenozide is a diacylhydrazine insecticide (Insecticide Resistance Action Committee (IRAC) Group 18) used on a variety of crops for control of armyworms and other lepidopterous pest species. Methoxyfenozide mimics the action of the molting hormone of lepidopterous larvae, causing the larvae to undergo an incomplete and developmentally lethal molt. Methoxyfenozide is currently registered to Dow AgroSciences for use on food or feed crops.

Uses and tolerances for methoxyfenozide have been established on a wide variety of crops, and in conjunction with these uses, tolerances have also been established on animal commodities and rotational crops (DP# 259549, M. Nelson, 07/AUG/2002; DP# 260888, M. Nelson, 07/AUG/2002). As a condition for the registrations on leafy and *Brassica* vegetables, stones fruits, corn and rotational crops, the Agency required the following data:

- Submission of multiresidue method testing data for metabolites RH-141,518; RH-117,236; RH-151,055; and RH-152,072.
- Submission of additional field trials on spinach (3 trials), celery (2 trials), mustard greens (3 trials) and plums (2 trials) at the labeled use rate.
- Submission of the residue data for metabolite RH-141,518 in fat and muscle from the poultry

feeding study, along with supporting storage stability data, and revise poultry tolerances as necessary.

- Submission of additional field accumulation trials in rotational crops.

In response to the above requirements, Dow AgroSciences has submitted multiresidue method testing data on the metabolites, spinach and plum field trials, rotational crop field trials, and a waiver request for the additional poultry residue data. The nomenclature of methoxyfenozide and its regulated metabolites is presented in Table 1, and the physicochemical properties of methoxyfenozide are listed in Table 2.

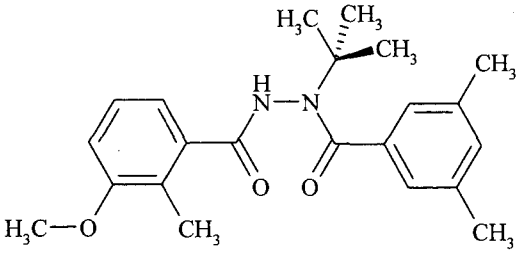
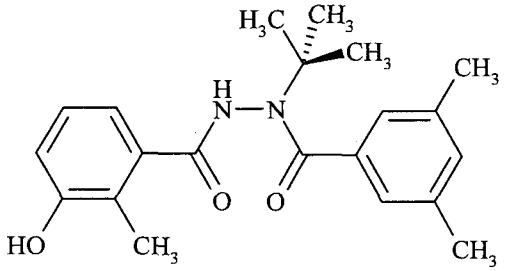
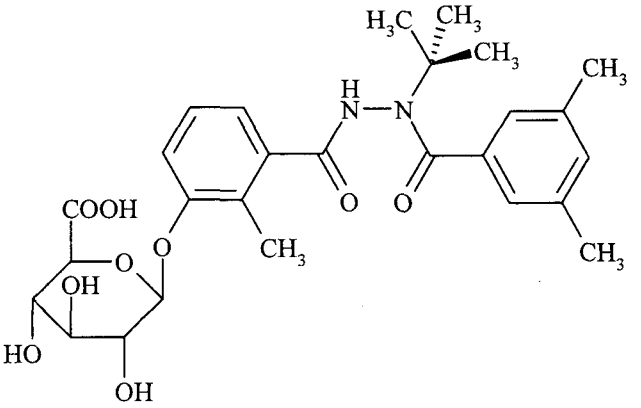
Table 1. Nomenclature of Methoxyfenozide and its Regulated Metabolites.	
Chemical structure	
Common name	Methoxyfenozide
Company experimental name	RH-2485
IUPAC name	N-*tert*-butyl-N′-(3-methoxy-*o*-toluoyl)-3,5-xylohydrazide
CAS name	3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide
CAS registry number	161050-58-4
Chemical structure	
Common name	Free phenol metabolite of methoxyfenozide
Company experimental name	RH-117,236
CAS name	3,5-dimethylbenzoic acid N -tert-butyl- N '-(3-hydroxy-2-methylbenzoyl) hydrazide
Chemical structure	

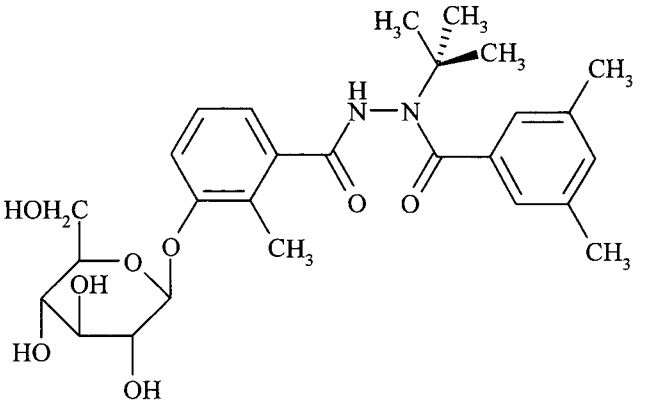
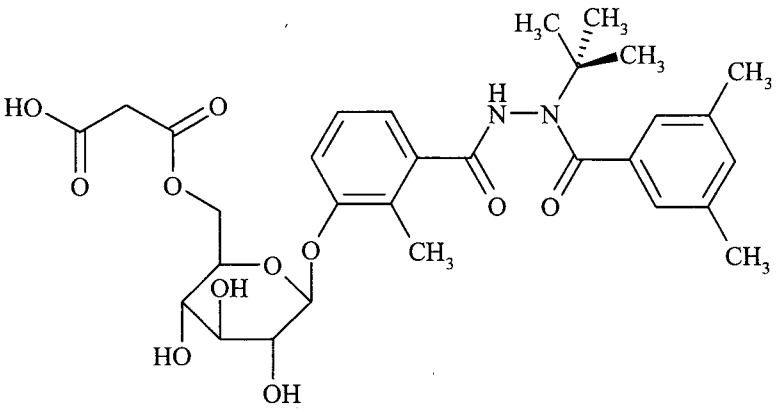
Table 1. Nomenclature of Methoxyfenozide and its Regulated Metabolites.	
Common name	Glucuronide conjugate of methoxyfenozide
Company experimental name	RH-141,518; Metabolite G
CAS name	β-D-Glucopyranuronic acid, 3-[2-(1,1-dimethylethyl)-2-(3,5-dimethylbenzoyl)-hydrazino]carbonyl-2-methylphenyl-]
Chemical structure	
Common name	Glucose conjugate of phenol metabolite
Company experimental name	RH-151,055; Metabolite J
CAS name	3,5-dimethylbenzoic acid N-tert-butyl-N-[3-(β-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide
Chemical structure	
Common name	Malonyl glucose conjugate of phenol metabolite
Company experimental name	RH-152,072; Metabolite H
CAS name	3,5-dimethylbenzoic acid N-tert-butyl-N′-[3-(β-D-6-malonyl-glucopyranosyl-1-oxy)-2-methylbenzoyl]-hydrazide

Table 2. Physicochemical Properties of Methoxyfenozide.		
Parameter	Value	Reference
Melting point/range	206.1-208°C	DP# 231303, H. Podall, 19/MAY/1997
pH	7.0	
Density	0.740 ± 0.0081 g.cm^3	
Water solubility (mg/L at 20°C)	3.3	
Solvent solubility (g/L at 20°C)	N-heptane 1.87 Xylene 3.38 1,2-dichloroethane 36.72 Methanol 192.92 2-Propanol 50.22	

Table 2. Physicochemical Properties of Methoxyfenozide.		
Parameter	Value	Reference
Vapor pressure at 25°C	1.33×10^{-5} Pa	
Dissociation constant, pK_a	None	
Octanol/water partition coefficient, $Log(K_{OW})$	3.72 ± 0.04	
UV/visible absorption (max)	ε 55313 at 203 nm	European Commission, SANCO/10384/202 – rev. 4, 10/07/2004.

860.1200 Directions for Use

Methoxyfenozide is currently registered to Dow AgroSciences for use on a wide variety of food and feed crops as a 2 lb/gal FlC formulation (Intrepid® 2F, EPA Reg. No. 62719-442) and as an 80% WP formulation (Intrepid™ 80WSP, EPA Reg. No. 62719-438). As the current uses on leafy greens and plums are the only primary crop uses being considered in this report, only the use patterns on these crops are summarized below in Table 3.

[1] Do not apply through any type of irrigation system

Table 3. Summary of Directions for Use of Methoxyfenozide.						
Applic. Timing, Type, and Equip. [1]	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations [2]
Leafy Vegetables						
Broadcast foliar applications at first signs of infestation; ground or air equipment	2 lb/gal FlC [62719-442]	0.06-0.25	NS	1.0	1	Minimum 10-day RTI is specified. Apply in a minimum of 10 and 20 gal/A using aerial or ground equipment, respectively. Non-ionic surfactant (NIS) adjuvant is allowed.
Stone Fruits						
Broadcast foliar applications at first signs of infestation; ground equipment only	2 lb/gal FlC [62719-442]	0.12-0.25	NS	1.0	7	Minimum 10-day RTI is specified. Apply in a minimum of 20 and 50 gal/A using aerial or ground equipment, respectively. NIS adjuvant is allowed.

[2] A 7-PBI is specified for rotational crops, which do not have any registered uses.
NS = Not Specified.

Conclusions. The label directions are adequate to allow evaluation of the residue data relative to the submitted field trials. The available field trial data support the current use directions and the use of adjuvants (non-ionic surfactant (NIS)). The available rotational crop field trials also support the label-specified 7-day PBI.

860.1300 Nature of the Residue - Plants

MARC Memo, DP# 258034, W. Wassell, 23/JUL/1999
DP# 251225, W. Wassell, 27/JUL/1999
DP# 259989, W. Wassell, 08/AUG/2000

The nature of methoxyfenozide residues in primary crops is adequately understood, based on acceptable metabolism studies in cotton, apples, grapes, and rice. Methoxyfenozide does not undergo extensive metabolism in primary crops. The MARC has determined that the residue of concern for both the tolerance expression and the risk assessment in primary crops (and drinking water) is methoxyfenozide *per se*.

860.1300 Nature of the Residue - Livestock

MARC Memo, DP# 258034, W. Wassell, 23/JUL/1999
DP# 251225, W. Wassell, 27/JUL/1999
DP# 269969, N. Nelson, 07/AUG/2002

The qualitative nature of methoxyfenozide residues in livestock is adequately understood based on available ruminant and poultry metabolism studies. Methoxyfenozide is metabolized primarily by oxidation in animals. One major pathway involves oxidation of the methyl group on the methoxyphenyl ring to form the corresponding phenol (RH-117,236). Additional oxidation of the methoxyphenyl ring, resulting in an additional phenolic moiety or oxidation of the dimethylphenyl ring to form hydroxymethyl groups or carboxylic acid, may also occur. The phenolic moiety was also subject to further conjugation with glucuronic acid (RH-141,518). In a minor pathway, the t-butyl moiety was subject to cleavage and incorporation into naturally occurring products such as lipids and lactose. The MARC determined that the residue of concern is parent in milk and ruminant tissues (except meat byproducts); the residues of concern in ruminant meat byproducts include methoxyfenozide and its glucuronide metabolite RH-141,518. In poultry, the residue of concern is parent in fat and meat, and the residues of concern in eggs and meat byproducts include methoxyfenozide and RH-141,518.

860.1340 Residue Analytical Methods

DP# 259549, M. Nelson, 07/AUG/2002

Enforcement methods for plant commodities. The following HPLC/UV (or MS) methods are available for enforcing tolerances of methoxyfenozide on primary crops: Method TR 34-96-88 for cotton commodities; Method TR 34-98-87 for pome fruits; Method TR 34–00-38 for corn commodities; Method TR 34-00-107 for tree nuts; Method TR 34-00-109 for stone fruits; and Method TR 34-99-74 for leafy and *Brassica* (cole) vegetables, fruiting vegetables, grapes and raisins. Adequate method validation, radiovalidation, and independent laboratory validation data have been provided for these methods. Successful petition method validation (PMV) trials were conducted on Methods TR 34-96-88 and TR 34-98-87, and Analytical Chemistry Branch (ACB) concluded that PMV trials were not required for the other methods as they are similar to the validated methods.

For each of these methods, residues of methoxyfenozide are extracted with acidic aqueous methanol, filtered and diluted with 10% sodium chloride. Extract are then purified by sequential

liquid-liquid partitioning with hexane and dichloromethane (DCM). Residues in the DCM fraction are further purified by elution through one or more of the following column types: basic alumina, silica gel, carbon, Florisil, or C_{18}. Residues in the final eluate are concentrated, redissolved in acetonitrile:water, and analyzed by reverse-phase HPLC using UV (240 nm) or MS (m/z 367) with external standards. The LOQ for methoxyfenozide is 0.01-0.05 ppm depending on the plant commodity.

An adequate enforcement method is also available for determining the residues of concern in rotated crops. Method TR 34-00-41 includes an HPLC/UV method that determines residues of methoxyfenozide in high-moisture rotational crops; and a HPLC/MS method that determined residues of methoxyfenozide and its metabolites RH-117,236, RH-151,055, and RH-152,072 (determined at RH-151,055) in low-moisture rotational crops. Adequate method validation, radiovalidation, and ILV data have been submitted for this method, and ACB concluded that a PMV trial was not needed for this method owing to its similarity to Method TR 34-98-87.

Data collection methods for plant commodities. Residues of methoxyfenozide in/on samples of spinach from the submitted spinach field trials were determined using the above HPLC/UV enforcement method (TR 34-99-74). The method was adequately validated in conjunction with the analysis of spinach field trial samples. The method LOQ is 0.02 ppm.

In the submitted plum field trials, residue of methoxyfenozide were determined using a LC/MS/MS method (Method GRM 02.25) that was adequately validated in conjunction with the analysis of field trial samples. For this method, methoxyfenozide residues are extracted with acidic methanol, diluted and purified using solid phase extraction (SPE), and then analyzed by LC/MS/MS. The validated LOQ is 0.020 ppm and the limit of detectioin (LOD) is 0.006 ppm.

In the submitted rotational crop field trials, residues of methoxyfenozide and its regulated metabolites in high- and low-moisture rotational crops were determined using the current tolerance enforcement method for rotational crops (Method TR 34-00-41). The method was adequately validated in conjunction with the analysis of the field trial samples. For high-moisture rotational crops, the validated LOQ for methoxyfenozide is 0.02 ppm. For low-moisture rotational crops, the validated LOQs are 0.02 ppm each for methoxyfenozide and RH-117,236 and 0.05 ppm for RH-151,055 (which includes RH-152,072). For reporting combined residues, residues of RH-117,236 and RH-151,055 were converted to parent equivalents by multiplying by 1.04 and 0.715, respectively. The LOQ for combined residues is 0.077 ppm in parent equivalents.

Conclusions. The available HPLC/UV (or MS) methods are adequate for enforcing the established or recommended tolerances, and residues in/on plums, spinach and rotational crops were determined using adequate data collection methods.

860.1360 Multiresidue Methods

DP# 251225, W. Wassell, 27/JUL/1999
46039301.der, D. Rate, 07/APR/2009

Data concerning the recovery of methoxyfenozide *per se* using the FDA multiresidue method protocols (PAM Vol. I) were previously reviewed. Methoxyfenozide was not recovered through

any of the multiresidue methods. The data were forwarded to FDA for evaluation and the updating of PAM Vol. I.

Dow AgroSciences has also submitted multiresidue method testing data on the four regulated metabolites of methoxyfenozide: the glucuronide animal metabolite RH-141,518; the free phenol metabolite RH-117,236; and the glucose and malonylglycosyl conjugates of RH-117,236 (RH-151,055 and RH-152,072).

Testing under Protocol A indicated that all four metabolites are fluorescent; however, only two metabolites (RH-117,236 and RH-151,055) chromatographed acceptably under the specified HPLC conditions, and these metabolites were not recovered from the required Celite/charcoal cleanup procedures. Therefore, testing through Protocol A was discontinued.

Metabolite RH-117,236 was tested through Protocol B as it has a phenol moiety. Its was shown to chromatograph acceptably using Level II conditions (230°C) with Module DG-10. However, the specified methylation procedures did not yield appreciable quantities of its methyl ether (RH-112,485; parent). Under Protocol C, Metabolites RH-141,518; RH-151,055; and RH-152,072 did not chromatograph acceptably on any of the column-detector combinations under Level I conditions; however, all four metabolites were shown to chromatograph acceptably under Level II conditions using Module DG-10. As electron capture detection was used for analysis, the recovery of each analyte was also evaluated from the Florisil column cleanup procedures under Protocols D and E. As none of the metabolites were recovered (<30%) from the required Florisil column cleanup, no further testing was conducted through Protocols D and E. Testing through Protocol G was not conducted as none of these metabolites are substituted urea compounds.

Conclusions. Data requirements for multiresidue method testing are fulfilled for parent and the regulated animal and rotational crop metabolites. Based on the available data, the FDA Multiresidue Methods are not suitable for analysis of methoxyfenozide and its regulated metabolites.

860.1380 Storage Stability

DP# 269986, M. Nelson, 07/AUG/2002
DP# 258155, W. Wassell, 20/AUG/1999

Adequate storage stability data are available indicating methoxyfenozide is stable under frozen conditions for up 6 months in corn meal and refined corn oil; 7.5 months in grapes; 9.4 months in apple juice; 10 months in apple wet pomace; 12 months in apples, cotton gin byproducts, cotton refined oil, and head lettuce; 12.2 months in tomatoes; 13.1 months in field corn grain; 23.5 months in cottonseed; and approximately 4 years in wheat forage.

The storage durations and conditions for the samples from the crop field trials submitted to support this petition are presented in Table 4.

Table 4. Summary of Storage Conditions and Durations of Samples from Crop Field Trial and Rotational Studies.

Matrix	Storage Temperature (°C)	Actual Storage Duration (months)	Interval of Demonstrated Storage Stability (months)

Table 4. Summary of Storage Conditions and Durations of Samples from Crop Field Trial and Rotational Studies.			
Matrix	Storage Temperature (°C)	Actual Storage Duration (months)	Interval of Demonstrated Storage Stability (months)
Spinach	-23 to -4	6-13	12
Plum	-20	6	12
Rotational Crops			
Soybean Forage	-20	10.7-14.3	48
Soybean Hay		9.8-13.6	48
Soybean Seed		6.5-12.1	23.5
Wheat Forage		10.1-12.6	48
Wheat Hay		8.8-11.0	48
Wheat Grain		7.7-10.3	13.1
Wheat Straw		7.8-10.5	48
Green Onion		8.2	12
Cucumber		8.6-9.1	12.2
Mustard Greens		4.8-17.1	12
Tomato		9.6-10.7	12.2
Turnip Tops		4.6-16.8	12
Turnip Root		4.6-16.8	12

Conclusions. The available storage stability data adequately support the sample storage conditions and intervals incurred in the submitted field trials.

860.1400 Water, Fish, and Irrigated Crops

There are no proposed uses that are relevant to this guideline topic.

860.1460 Food Handling

There are no proposed uses that are relevant to this guideline topic.

860.1480 Meat, Milk, Poultry, and Eggs

DP# 249438, W. Wassell, 27/JUL/1999
DP# 269969, N. Nelson, 07/AUG/2002

The potential dietary exposure of livestock to methoxyfenozide residues was calculated using the Agency's most recent guidance for constructing reasonably balanced diets for livestock (Memo, Chemistry Science Advisory Council (ChemSAC), 30/JUN/2008), along with the current and recommended tolerances for livestock feedstuffs. The MDB of livestock for methoxyfenozide residues was calculated to be 74 ppm for beef cattle, 62 ppm for dairy cattle, 0.94 ppm for poultry, and 0.99 ppm for swine (Table 5).

Table 5. Calculation of Dietary Burdens of Methoxyfenozide Residues to Livestock.					
Feedstuff	Type[1]	% Dry Matter[2]	% Diet[2]	Tolerance (ppm)	Dietary Contribution (ppm)[3]
Beef Cattle					
Corn, field, stover	R	83	25	125	37.65

Table 5. Calculation of Dietary Burdens of Methoxyfenozide Residues to Livestock.					
Feedstuff	Type[1]	% Dry Matter[2]	% Diet[2]	Tolerance (ppm)	Dietary Contribution (ppm)[3]
Sorghum, grain, stover	R	88	15	125	21.31
Alfalfa, meal	PC	89	15	8.0	1.35
Apples, wet pomace	C	40	20	7.0	3.50
Corn, field, grain	C	86	10	0.05	0.006
Turnip, root	C	15	10	0.50	0.33
Soybean, aspirated grain fractions	C	85	5	160	9.41
TOTAL BURDEN	--	--	100	--	**73.6**
Dairy Cattle					
Corn, field, stover	R	83	15	125	22.59
Sorghum, grain, stover	R	88	15	125	21.31
Turnip, tops	R	30	15	30	15.0
Alfalfa, meal	PC	89	15	8.0	1.35
Corn, field, grain	C	86	20	0.05	0.012
Apples, wet pomace	C	40	10	7.0	1.75
Turnip, root	C	15	10	0.5	0.33
TOTAL BURDEN	--	--	100	--	**62.3**
Poultry					
Alfalfa, meal	PC	NA	10	8.0	0.800
Soybean, seed	PC	NA	10	1.0	0.100
Corn, field, grain	C	NA	70	0.05	0.035
Sorghum, grain	C	NA	10	0.05	0.005
TOTAL BURDEN	--	--	100	--	**0.940**
Swine					
Alfalfa, meal	PC	NA	10	8.0	0.800
Soybean, seed	PC	NA	15	1.0	0.150
Corn, field, grain	C	NA	75	0.05	0.038
TOTAL BURDEN	--	--	100	--	**0.988**

[1] R: Roughage; C: Carbohydrate concentrate; P: Protein concentrate.
[2] OPPTS 860.1000 Table 1 Feedstuffs (October 2006).
[3] Contribution = ([tolerance /% DM] X % diet) for beef and dairy cattle; contribution = ([tolerance] X % diet) for poultry and swine.
[4] The available processing studies indicate that residues are reduced in both cottonseed meal (0.14x) and soybean meal (0.06x); therefore, the tolerance for cottonseed (2 ppm) was adjusted accordingly.

Adequate cattle and poultry feeding studies have been previously reviewed in conjunction with the petitions for tolerances on pome fruits and field corn. However, previously as a condition of registration, HED required data on residues of RH-141,518 in fat and meat from the poultry feeding study, along with supporting storage stability data.

In response, Dow AgroSciences has requested a waiver for residue data on RH-141,518 in poultry fat and meat. The registrant indicated that given the age of the feeding study, which is now over 8 years old, and concerns about the stability of RH-141,518 in animal tissues, any information produced by reanalysis of the fat and meat samples is likely to be unreliable. In addition, Dow noted that sufficient data are already available from the existing poultry metabolism and feeding studies to conclude that residues of RH-141,518 are unlikely to be detectable in meat and fat at dose levels up to 20 ppm.

In the original poultry feeding study, laying hens were dosed orally with methoxyfenozide via gelatin capsules once daily for 28 consecutive days, at actual dose levels equivalent to 2.37, 7.58, and 23.5 ppm in their diet. These dose levels are equivalent to 2.5x, 7.3x, and 25x the MDB for poultry. Eggs were collected throughout the dosing period, and the hens were sacrificed within 24 hours of receiving the final dose. Samples of muscle (breast + thigh), liver and fat were collected from each hen and pooled to yield triplicate composited samples for each matrix from each dose group. Samples of eggs and liver were analyzed for both parent and RH-141,518; but samples of meat and fat were only analyzed for parent.

At the highest dose level (25x MDB), residues of parent were detected in only one egg sample on day 10, and were non-detectable all samples of liver, muscle and fat. Residues of RH-141,518 were detected in eggs from days 7 through 28 (0.0021-0.0050 ppm), plateauing by day 10. In liver, residues of RH-141,518 were 0.0146-0.0297 ppm.

When results from the feeding study are compared to the poultry metabolism study, the two studies show the same distribution of parent and RH-141,518 residues in eggs and liver (Table 6). In the metabolism study, in which the hens were dosed at levels equivalent to ~58 ppm (62x MDB), residue levels of RH-141,518 were ~10x higher than parent in eggs and liver; however, residues of parent were higher in fat and muscle than residues of RH-141,518. In the feeding study, residue levels of RH-141,518 were also higher than parent in eggs and liver. Although RH-141,518 was not determined in fat and meat samples from the feeding study, the residue data on meat and fat from the metabolism study, along with fact that parent was non-detectable in meat and fat from the feeding study, indicates that residues of RH-141,518 are very unlikely to be detectable in fat and meat from the feeding study.

Based on the available poultry data, ARIA concurs that residues are likely to be non-detectable in poultry dosed at up to 25x the MDB; therefore, reanalysis of the feeding studies will not be required at this time.

Table 6. Comparison of Results from the Poultry Feeding Study and Poultry NOR Study for Residues of Methoxyfenozide and Metabolite RH-141,518.

Commodity	Residues (ppm) from Poultry Feeding Study; Dose level 23.5 ppm (25x the MDB)		Residues (ppm) from Poultry MOR study; Dose level ~58 ppm (62x the MDB)	
	Methoxyfenozide	**RH-141,518**	**Methoxyfenozide**	**RH-141,518**
Eggs	ND-0.0054	0.0021-0.0050	0.001-0.003	0.014-0.032
Fat	ND [1]	Not Analyzed	0.017-0.032	0.001-0.007
Muscle	ND	Not Analyzed	0.001-0.003	<LOD-0.001
Liver	ND	0.0146-0.0297	0.004-0.006	0.052-0.066

[1] ND – not detected; the LOD in the feeding study was 0.003 ppm for parent and 0.0021 for RH-141,518 (expressed in parent equiv.).

Conclusions. Considering the MDB for poultry (0.94 ppm) and the available residue data from both the poultry feeding study and poultry metabolism study, residues of RH-141,518 are unlikely to be detectable in poultry fat or meat at dosing levels up to 25x the MDB. Therefore, pending an increase in the poultry MDB, ARIA will waive the previous requirement for the analysis of poultry fat and meat for residues of RH-141,518. The existing tolerances for livestock commodities are adequate.

860.1500 Crop Field Trials

DP# 260888, M. Nelson, 07/AUG/2002
DP# 274516, M. Nelson, 07/AUG/2002
46606301.der (plums), D. Rate, 07/APR/2009
45870501.der (spinach), D. Rate, 07/APR/2009

As a condition of registration for uses on leafy vegetables, *Brassica* vegetables and stone fruits, the Agency required submission of three additional field trials on spinach in EPA growing Regions 1, 2, and 10, two additional two field trials on celery in EPA growing Region 3, three additional field trials on mustard greens in EPA growing Regions 2, 3, and 10, on two additional trials on plums in EPA growing Regions 10 and 11 (DP# 274516, M. Nelson, 07/AUG/2002; DP# 260888, M. Nelson, 07/AUG/2002). In response, Dow AgroSciences has submitted the requested plum and spinach field trials. The results from these field trials discussed below and summarized in Table 7, along with the adequate residue data from the earlier field trials on plums and spinach.

Table 7. Summary of Residue Data from Crop Field Trials with Methoxyfenozide (FlC and WDG).

Crop matrix (MRID)	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm) [1]						
			n	Min.	Max.	HAFT [2]	Median	Mean	Std. Dev.
Leafy Vegetables (proposed use = 1.0 lb ai/A total application rate, 1-day PHI)									
Spinach (45870501)	1.00-1.03	1	6	5.40	11.00	9.99	7.81	7.81	2.28
Spinach (44924304)	1.00	1	10	9.68	17.80	17.18	13.30	13.63	3.32
Combined	1.00-1.03	1	16	5.40	17.80	17.18	10.65	11.44	4.10
Stone Fruits (proposed use = 1.0 lb ai/A total application rate, 7-day PHI)									
Plum (46606301)	0.99-1.07 [3]	7	4	0.14	0.50	0.43	0.29	0.31	0.16
Plum (45213304)	1.82-1.84 [4]	6-8	14	0.10	0.36	0.34	0.18	0.20	0.09
Combined	0.99-1.83 [5]	6-8	18	0.10	0.50	0.43	0.19	0.23	0.11

[1] The validated LOQ for methoxyfenozide is 0.02 ppm.
[2] HAFT = Highest average field trial result.
[3] In the new plum field trials, four applications were made at 0.25 lb ai/A (1x single rate) for a total of ~1.0 lb ai/A (1x total rate).
[4] In the older plum field trials, four applications were made at ~0.3 lb ai/A (1.2x single rate) for a total of ~1.8 lb ai/A (1.8x total rate).
[5] Because the single applications were made at a 1.2x rate in the earlier trials, the original residue values from these field trials were not be corrected to a 1x level as the final 4 applications would account for the majority of measured residues.

Leafy Greens Subgroup 4A

Spinach. Residue data from six spinach field trials were submitted with the original petition for uses on leafy greens (subgroup 4A). However, three of the field trials were determine to have been conducted under non-commercial conditions; therefore, the data from these field trials were not used for tolerance assessment; and three additional spinach field trials were required.

In the three adequate spinach field trials conducted in EPA growing Regions 6, 9 and 10, methoxyfenozide (WP or FlC) was applied to spinach as four broadcast foliar applications during vegetative development at 0.25 lb ai/A/application at RTIs of 7-14 days, for a total of 1.00 lb ai/A (1x rate). Side-by-side field trials comparing the use of the 80% WP and 2 lb/gal FlC

formulations were conducted at two trial sites, and only the 80% WP was used at the third trial site, for a total of five field trials. Applications were made using ground equipment at volumes of 14-58 gal/A, and included the use of an NIS adjuvant. Single control and duplicate treated samples of spinach were harvested from each trial at 1 day after treatment (DAT) and were stored frozen for up to 7.9 months prior to extraction for analysis. Samples were analyzed for residues of methoxyfenozide using an adequate HPLC/UV method (TR 34-99-74). The validated LOQ was 0.02, and the LOD is 0.006 ppm.

Residue levels were similar for the two formulations. Following applications totaling 1.0 lb ai/A (1x rate), methoxyfenozide residues were 9.68-17.8 ppm in/on 10 samples of spinach harvested at 1 DAT. Average residues at 1 DAT were 13.63 ppm and the HAFT residues were 17.2 ppm.

In the three newer field trials conducted during 1999-2000 in EPA growing Regions 1, 2, and 10, methoxyfenozide (80% WP) was applied to spinach as four broadcast foliar applications during vegetative development at 0.25-0.26 lb ai/A/application at RTIs of 7-10 days, for a total of 1.00-1.03 lb ai/A (1x rate). Applications were made using ground equipment at volumes of 16-46 gal/A, and included the use of a NIS adjuvant. Single control and duplicate treated samples of spinach were harvested from each field trial at 1 DAT, and additional samples were collected from one field trial at 0, 3, 7 and 10 DAT to assess residue decline. Samples were stored frozen for up to 13 months prior to extraction for analysis, an interval supported by the available storage stability data. Residues in/on spinach were determined using the adequate HPLC/UV method (TR 34-99-74). The validated LOQ is 0.02 ppm in spinach, and the LOD is 0.006 ppm.

Following four applications totaling 1.00-1.03 lb ai/A (1x rate), residues of methoxyfenozide were 5.4-11.0 ppm in/on 6 samples of spinach harvested at 1 DAT. Average residues at 1 DAT were 7.81 ppm and the HAFT residues were 9.99 ppm. Data from the residue decline trial showed that average methoxyfenozide residues were relatively unchanged from 0 to 10 DAT.

Fruit, stone, group 12

Adequate field trail data on peach and cherries were submitted with the original petition for use of methoxyfenozide on stone fruits (DP# 274516, M. Nelson, 07/AUG/2002). This petition also included adequate field trial data from six plum field trials. However, because it was determined that a separate tolerance should be established for plums, the Agency requested an additional two plum field trials.

Plum, fresh prunes. In the original six plum field trials (45213304.der) conducted in EPA growing Regions 5, 10, 12, methoxyfenozide (WP or FlC) was applied to plums as six broadcast foliar applications during fruit development at 0.299-0.309 lb ai/A/application at RTIs of 6-34 days, for a total of 1.82-1.84 lb ai/A. The single application rate in these field trials is equivalent to 1.2x the maximum labeled single use rate and the total rate is equivalent to 1.8x the maximum seasonal rate. Side-by-side field trials comparing the use of the 80% WP and 2 lb/gal FlC formulations were conducted at one trial site, and the 80% WP was used at the remaining sites, for a total of seven field trials. Applications were made using ground equipment, and included the use of a NIS adjuvant. Single control and duplicate treated samples of plums were harvested from each field trial at 6-8 DAT and were stored frozen for up to 14.5 months prior to extraction for analysis. Samples were analyzed for residues of methoxyfenozide using an adequate

HPLC/UV method (TR 34-99-26). The validated LOQ was 0.02.

Residue levels were similar for the two formulations. Following applications totaling ~1.8 lb ai/A (1.8x rate), methoxyfenozide residues were 0.10-0.36 ppm in/on 14 samples of plums harvested at 6-8 DAT. Average residues at ~7 DAT were 0.20 ppm and the HAFT residues were 0.34 ppm. Although the seasonal use rate in the original trials was 1.8x the maximum labeled rate, the single use rate (~0.3 lb ai/A) was only 1.2x the maximum single use rate. As methoxyfenozide has been shown to decline at longer post-treatment intervals in a variety of crops, the final 4 applications are likely to account for the majority of the residues. Because the single application were made at a 1.2x rate, the original residue values from these field trials will not be corrected to a 1x rate for purposes of assessing the tolerance level.

In the two additional plum field trials conducted in EPA growing Regions 10 and 11 during 2004 (46606301.der), methoxyfenozide (2 lb/gal FlC) was applied to plum trees as four broadcast foliar applications during fruit development and maturation, at rates of 0.25-0.27 lb ai/A/application (1x single rate) at RTIs of 10-13 days, for a total of 0.99-1.07 lb ai/A (1x seasonal rate). Applications were made using ground equipment at volumes of 60-77 gal/A, and included the use of a NIS adjuvant at 0.1% v/v. Single control and duplicate treated samples of plums were harvested from each trial site at 7 DAT, and samples were stored frozen for up to 6 months prior to extraction for analysis.

The LC/MS/MS method (Method GRM 02.25) used for determining residues of methoxyfenozide in/on plums was adequately validated in conjunction with the analysis of field trial samples. The validated LOQ is 0.020 ppm, and the LOD is 0.006 ppm.

Following the last of four broadcast foliar applications of methoxyfenozide (FlC) totaling 0.99-1.07 lb ai/A (1x rate), residues of methoxyfenozide were 0.14-0.50 ppm in/on 4 samples of plums harvested at 7 DAT. Average residues were 0.31 ppm and the HAFT residues were 0.43 ppm.

When the data from all eight adequate plum field trials are combined, residues of methoxyfenozide were 0.10-0.50 ppm in/on 18 samples of plums harvested at ~7 DAT. Average residues were 0.23 ppm and the HAFT residues were 0.43 ppm.

Conclusions. The new spinach and plum field trial data are adequate, and together with the earlier field trials provide an adequate number of field trials and geographic representation for spinach and plums. When considered together, the old and new spinach field trials support the labeled use rate and the current 30 ppm tolerance for the leafy greens subgroup (4A) as determined by the NAFTA Maximum Residue Limit (MRL) calculator. The residue data from all the available plum field trials support the labeled use rate; however, the MRL calculator indicates that the tolerance for plums should be increased to 0.6 ppm. A revised section F should be submitted requesting a tolerance of 0.6 ppm for plum, prune, fresh corresponding to the recommended tolerance and commodity definition.

The requested residue data on celery (2 field trials) and mustard greens (3 field trials) remain outstanding as a condition of registration.

860.1520 Processed Food and Feed

DP# 274516, M. Nelson, 07/AUG/2002

An adequate plum processing study is available indicating that residues do not concentrate substantially (<1.2x) in/on prunes. There are currently no outstanding requirements for processing data.

860.1650 Submittal of Analytical Reference Standards

Analytical reference standards for methoxyfenozide and Metabolites RH-117,236, RH-151,055, RH-152,072, and RH-141,518 are currently available at the EPA National Pesticide Standards Repository (personal communication with D. Wright, ACB, 05/FEB/2008). However, the standard for RH-141,518 expired on 01/DEC/2004. The registrant must either recertify the lot in the repository and send in an updated certificate of analysis (COA), or submit a new standard (different lot #) if the previous lot will not be recertified. If a new COA is being submitted, it should be faxed to the repository at 410-305-2999.

If new standards are being submitted, they should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, to the attention of either Theresa Cole or Frederic Siegelman at the following address:

USEPA
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
701 Mapes Road
Fort George G. Meade, MD 20755-5350

(Note that the mail will be returned if the extended zip code is not used.)

860.1850 Confined Accumulation in Rotational Crops

MARC Memo, DP# 258034, W. Wassell, 23/JUL/1999
DP# 251225, W. Wassell, 27/JUL/1999

The nature of methoxyfenozide residues in rotational crops is adequately understood, based on the available confined rotational crop study. Following three soil applications of ^{14}C-methoxyfenozide at rates totaling 2.0 lb ai/A (1x rate), total radioactive residues accumulated at ≥0.01 ppm in mustard, radishes, and wheat planted 31, 91, and 364 days after the last application. Methoxyfenozide was highly metabolized in rotational crops by oxidation, demethylation, and hydroxylation to non-conjugated metabolites, which were then conjugated with biomolecules yielding bound residues and precursors in the sugar synthesis pathway.

HED previously concluded that the residues of concern in rotational crops include methoxyfenozide, its free phenol metabolite (RH-117,236), conjugated forms of the phenol metabolite (RH-151,055 and RH-152,072), and the metabolites RH-152,067; RH-131,157; and RH-152,071. For enforcement purposes, the tolerance definition for rotated crops includes only parent in high-moisture crops and the combined residues of parent and metabolites RH-151,055;

RH-152,072; and RH-117,236 in low-moisture crops. Metabolites RH-152,067; RH-131,157; and RH-152,071 are also to be taken into account in risk assessments.

860.1900 Field Accumulation in Rotational Crops

DP# 269986, M. Nelson, 07/AUG/2002

Label directions for methoxyfenozide currently specify the following rotational crop restriction: crops with registered uses may be replanted at any time, and all other food or feed crops may be replanted 7 days after the last application.

Limited field trials. Adequate limited field rotational crop studies were submitted supporting the labeled 7-day PBI. In two field trials conducted in EPA growing Regions 6 and 10, methoxyfenozide (80% WP) was applied to a primary crop of leaf lettuce as five broadcast foliar applications at 0.4 lb ai/A/application and RTIs of 7-10 days, for a total of 2.0 lb ai/A, which is 2x the maximum seasonal rate for field and vegetable crops. The primary crop was harvested 1-3 days after the last application, and the following rotational crops were planted at both sites within 7 days of the last application: mustard greens, tomato, cucumber, turnip, wheat, soybean, and onion. The appropriate raw agricultural commodities were collected from each crop at normal maturity.

High-moisture crops (mustard greens, turnip tops, turnip roots, onions, cucumbers, and tomatoes) were analyzed for residues of methoxyfenozide *per se* using an adequate HPLC/UV data collection method (TR 34-98-186). Commodities from low-moisture crops (wheat and soybean) were analyzed for residues of parent and metabolites RH-117,236 and RH-151,055, RH-152,072 (determined as RH-151,055) using the HPLC/MS enforcement method (TR 34-00-28).

For the high-moisture crops, residues of methoxyfenozide were <0.02 ppm in all samples of cucumber and tomatoes, <0.02-0.055 ppm in onions, <0.02-0.023 ppm in turnips roots, 0.025-0.070 ppm in turnip tops, and 0.092-0.138 ppm in mustard greens. In the low-moisture crops, the combined residues of methoxyfenozide, RH-117,236, RH-151,055 and RH-152,072 (expressed in parent equivalents) were 0.68-1.39 ppm in wheat forage, 1.49-4.61 ppm in wheat hay, 1.39-6.39 ppm in wheat straw, <0.077 ppm in wheat grain, 0.70-4.28 ppm in soybean forage, 0.20-7.11 ppm in soybean hay, and <0.089 ppm in soybean seeds.

Based on the results of these limited studies, the Agency required extensive rotational crop field trials as a condition for registration for methoxyfenozide (DP# 269986, M. Nelson, 07/AUG/2002).

Extensive field trials. Dow AgroSciences has submitted 12 field rotational crop trials conducted in EPA growing Regions 2, 4, 5, 7, 8, and 11 during 2000. These trials were conducted in a manner similar to the limited studies, except that each rotational crop was not planted at each site. In each field trial, methoxyfenozide (80% WP) was applied to a primary crop of leaf lettuce as five broadcast foliar applications during vegetative development at rates of 0.39-0.41 lb ai/A/application and RTIs of 7-10 days, for a total of 1.99-2.02 lb ai/A (2x maximum seasonal rate). Applications were made using ground equipment at volumes of 10-32 gal/A, and include the use of a NIS adjuvant at 0.18-0.25% of the spray volume. The primary

lettuce crop was harvested 1-3 days after the final application, and the representative rotational crops of soybeans, wheat, onions, cucumbers, mustard greens, tomatoes and turnips were planted 6-10 days after the last application (~7-day PBI). The numbers of field sites planted with each crop were as follows: 6 sites each for soybeans and wheat, 4 sites for turnips, 3 sites for mustard greens, 2 sites each for cucumbers and tomatoes, and 1 site for green onions. The rotational crops were grown according to standard agricultural practices, and harvested at the appropriate stage of maturity.

Single control and duplicate treated samples of each RAC were collected at normal maturity; 89-270 days after planting (DAP) for wheat forage, 138-307 DAP for wheat hay, 161-339 DAP for wheat grain and straw, 38-60 DAP for soybean forage, 58-105 DAP for soybean hay, 103-146 DAP for soybean seed, 47-112 DAP for turnip tops and roots, 41-112 DAP for mustard greens, 51-62 DAP for cucumber, 45-107 DAP for tomato, and 70 DAP for onions. Samples were stored frozen for up to 17.1 months prior to analysis, an interval supported by available storage stability data.

Residues of methoxyfenozide and its regulated metabolites in high- and low-moisture rotational crops were determined using an HPLC/UV or MS method (Method TR 34-00-41), which is the current tolerance enforcement method for rotational crops. The method was adequately validated in conjunction with the analysis of field trial samples. The lowest level of method validation (LLMV) for methoxyfenozide in high-moisture crops is 0.02 ppm, and the reported LOD is 0.006 ppm. For low-moisture crops, the LLMV for methoxyfenozide and RH-117,236 each is 0.02 ppm, and the LOD is 0.006 ppm. The LLMV for RH-151,055 in low-moisture crops is 0.05 ppm, and the LOD is 0.015 ppm. For reporting combined residues, residues of RH-117,236 and RH-151,055 are converted to parent equivalents by multiplying by 1.04 and 0.715, respectively. The LOQ for combined residues is 0.077 ppm

Residues of methoxyfenozide *per se* were <LOQ (<0.02 ppm) in all samples of wheat forage and grain, soybean seeds, turnip roots, tomatoes and cucumbers. Methoxyfenozide residues were <0.02-0.022 ppm in wheat hay, <0.02-0.023 ppm in wheat straw, <0.02-0.077 in soybean forage, <0.02-0.136 ppm in soybean hay, <0.03-0.038 ppm in turnip tops, <0.02-0.031 ppm in mustard greens and 0.028-0.060 ppm in onions. Average residues of parent were 0.02 ppm in wheat forage, hay, straw and grain, as well as, soybean seeds, turnip roots, cucumber and tomato. Average parent residues were 0.044 ppm in soybean forage and green onions, 0.064 ppm in soybean hay, and 0.022 ppm in turnip tops and mustard greens.

In the low-moisture crops (wheat and soybean), substantial amounts of both the phenol metabolite (RH-117,236) and the sugar conjugates (RH-151,055 + RH-152,072) were detected in each commodity except wheat grain. Maximum residues of RH-117,236 were 0.038 ppm in wheat forage, 0.510 ppm in wheat hay, 0.841 ppm in wheat straw, 0.058 ppm in soybean forage, and 0.218 ppm in soybean hay. Maximum residues of RH-151,055/RH-152,072 were 1.318 ppm in wheat forage, 0.857 ppm in wheat hay, 0.845 ppm in wheat straw, 0.376 ppm in soybean forage, 0.907 ppm in soybean hay, and 0.768 ppm in soybean seeds.

In the low-moisture crops, combined residues of methoxyfenozide, RH-117,236 and RH-151,055/RH-152,072 (expressed in parent equivalents) were 0.106-1.002 ppm in wheat forage, 0.274-0.912 ppm in wheat hay, <LOQ (<0.077 ppm) in wheat grain, 0.329-1.278 ppm in wheat

straw, <0.077-0.359 ppm in soybean forage, <0.077-0.738 ppm in soybean hay, and <0.077-0.590 ppm in soybean seed. Average combined residues were 0.481 ppm in wheat forage, 0.539 ppm in wheat hay, <0.077 ppm in wheat grain, 0.710 ppm in wheat straw, 0.207 ppm in soybean forage, 0.468 ppm for soybean hay, and 0.143 ppm for soybean seed.

As the application rates and procedures from the two limited field trials were the same as in the extensive field trials, the residues data from the two limited trials have been combined with the 12 extensive field trials for determining tolerances for inadvertent or indirect residues. The combined data are reported below in Table 8.

TABLE 8. Summary of Residue Data from Limited and Extensive Rotational Crop Field Trials with Methoxyfenozide. [1]

Rotational Crop Commodity	Applic. Rate (lb ai/A)	PBI (days)	Residue Levels (ppm) [2]						
			n	Min.	Max.	HAFT [3]	Median (STMdR)	Mean (STMR)	Std. Dev.
Methoxyfenozide									
Turnip Roots	1.99-2.02	6-10	12	<0.020	0.023	0.022	0.020	0.020	0.001
Turnip Tops			12	<0.020	0.070	0.064	0.020	0.030	0.017
Mustard Greens			10	<0.020	0.138	0.118	0.026	0.056	0.045
Cucumber Fruit			8	<0.020	<0.020	<0.020	0.020	0.020	NA
Tomato Fruit			8	<0.020	<0.020	<0.020	0.020	0.020	NA
Onions			6	<0.020	0.060	0.055	0.041	0.040	0.019
Combined Residues [4]									
Wheat Forage	1.99-2.02	6-10	16	0.106	1.391	1.212	0.578	0.602	0.344
Wheat hay			16	0.274	4.614	3.350	0.601	1.013	1.086
Wheat Grain			16	<0.077	<0.077	<0.077	0.077	0.077	NA
Wheat Straw			16	0.392	6.390	4.383	0.787	1.263	1.466
Soybean Forage			16	0.077	4.284	3.749	0.221	0.712	1.216
Soybean hay			16	0.077	7.105	5.377	0.475	1.051	1.815
Soybean seed			16	0.077	0.590	0.472	0.077	0.127	0.141

[1] Residue data are from both the limited (MRID 45194701) and extensive (MRID 45870502) rotational crop field trials.
[2] The validated LOQ is 0.02 ppm for methoxyfenozide and 0.077 ppm for combined residues. The LOQ was used for residue values of <LOQ in all calculations.
[3] HAFT = Highest Average Field Trial.
[4] Combined residues are expressed in parent equivalents. For combining residues, residues of RH-117,236 and RH-151,055 (which includes RH-152,072) were converted to parent equivalents by multiplying by 1.04 and 0.715, respectively.

Conclusions. The available rotational crop field trials are adequate for purposes of assessing inadvertent or indirect tolerances on rotational crops. Although the required number of field trials was not conducted for each crop, the field trials were conducted at 2x the maximum seasonal use rate on field and vegetable crops. Therefore, the residue data will serve as a conservative estimate of residues in rotational crops. In addition, rotational crop residue data are no longer required for tomato, cucumber, and mustard greens as primary crop tolerances have been established on the crop groups for which these crops would serve as representative crops. Primary crop tolerances for methoxyfenozide are established for cucurbit and fruiting vegetables (crop groups 8 and 9), leafy vegetables (subgroups 4A and 4B), Brassica vegetables (subgroups 5A and 5B), leaves of root and tuber vegetables (crop group 2), and foliage of legume vegetables (subgroup 7A and soybean forage and hay).

Rotational crop tolerances are now required on only the following crop groups or subgroups: tuberous and corm vegetables (subgroup 1C); bulb vegetables (crop group 3); dried shelled peas

and beans, except soybean (subgroup 6C); cereal grains (crop group 15); forage, fodder and straw of cereal grains (crop group 16); grass forage, fodder and hay (crop group 17); nongrass animal feeds (crop group 18); herbs and spices (crop group 19), and oil seeds (crop group 20). The following paragraphs address the tolerance reassessments for these crop groups or subgroups.

For the high-moisture crops, the available rotational crop data on turnip roots will support a 0.05 ppm tolerance for methoxyfenozide on tuberous and corm vegetables (subgroup 1C), and the available residue data on onions will support reducing the existing tolerance for methoxyfenozide on bulb vegetables to 0.1 ppm. A revised section F must be submitted to accommodate the proper commodity definitions and recommended tolerances as specified above and in Table 9.

For the low-moisture crops, the available residue data on wheat grain indicate that a rotational crop tolerance for cereal grains (crop group 15) is not necessary, as residues were <LOQ in/on all samples of wheat grain following a 2x application to the primary crop. The available rotational crop data on wheat forage, hay and straw will support a tolerance of 6.0 ppm for forage, fodder and straw of cereal grains (crop group 16). These data will also support a 6.0 ppm tolerance for combined residues in grasses (crop group 17), and the wheat forage and hay data will support a tolerance of 4.5 ppm for herbs and spices (crop group 19). Although rotational crop tolerances are not required for soybean commodities, the available rotational crop residue data on soybean seeds will support 1.0 ppm tolerances on dried shelled peas and beans, except soybean (subgroup 6C) and oil seeds (crop group 20). The available soybean forage and hay residue data will also support reducing the tolerance on nongrass animal feeds (crop group 18) to 8 ppm. A revised section F must be submitted to accommodate the proper commodity definitions and recommended tolerances as specified above and in Table 9.

860.1550 Proposed Tolerances

For uses on primary crops, the methoxyfenozide assessment team concurs with HED's previous finding regarding the residue of concern in plant commodities (methoxyfenozide *per se*). Permanent tolerances are established for methoxyfenozide *per se* on a wide variety of plant commodities at levels ranging from 0.05 ppm in/on field corn grain and sweet corn ears to 160 ppm in/on soybean aspirated grain fractions [40 CFR §180.544(a)(1)]. The current tolerances on the leaf greens subgroup 4A and plums are listed in Table 9.

The available spinach and plum field trial data are adequate for assessing tolerances. Adequate residue data are available from 8 spinach field trials conducted at 1x the labeled use rate using either a WP or FlC formulation of methoxyfenozide. Adequate residue data are also available from a total of 9 plum field trials using either the WP or FlC formulation. Two of these field trials were conducted at the 1x use rate, and the other 7 field trials were conducted at 1.8x the maximum seasonal rate. However, the single use rate in these 7 field trials was 1.2x the maximum single use rate. As the final 4 applications are likely to account for the majority of residues, the residue data in these field trials can be considered to represent a 1.2x use rate. Therefore, the residue data from all 9 plum field trials will be combined to assess the tolerance for plums.

Because methoxyfenozide residues were >LOQ in all spinach and plum samples, the Agency's *Guidance for Setting Pesticide Tolerance Based on Field Trial Data* was utilized for determining

appropriate tolerance levels on spinach and plums (Appendix II). Using the MRL calculator, the recommended tolerances for spinach and plums were 30 and 0.6 ppm, respectively. Therefore, no revision is required for the current tolerance on leafy greens, subgroup 4A (30 ppm); however, the tolerance on plums should be increased to 0.6 ppm. Therefore, a revised section F must be submitted to request the recommended tolerance of 0.6 ppm in/on plum, prune fresh, as specified above and in Table 9.

For residues in livestock commodities, HED determined that the residue of concern is parent in milk and fat and meat of livestock and poultry. The residues of concern in eggs and meat byproducts of livestock and poultry include methoxyfenozide and its glucuronide metabolite RH-141,518. Permanent tolerances are established for methoxyfenozide *per se* in milk, meat, fat of livestock at 0.02-0.50 ppm fractions [40 CFR §180.544(a)(1)], and permanent tolerances are established for the combined residues of parent and RH-141,518 in eggs and meat byproducts at 0.02-0.40 ppm [40 CFR §180.544(a)(2)]. Based on the calculated dietary burden for cattle, hogs and poultry, and the data from the existing metabolism studies and feeding study, the current tolerances for livestock commodities are adequate.

For enforcement purposes, the tolerance definition for rotational crops includes only parent in high-moisture crops and the combined residues of parent and metabolites RH-117,236, RH-151,055 and RH-152,072 (determined as RH-151, 055) in low-moisture crops.

The available rotational crop field trials are adequate for assessing rotational crop tolerances. Although the required number of rotational crop field trials was not conducted for each crop, geographic distribution of the field trials was adequate and the field trials were conducted at a 2x rate. Therefore, the residue data will serve as a conservative estimate of residues in rotational crops.

Considering all the primary crop tolerances, rotational crop tolerances are required for only the following crop groups or subgroups: tuberous and corm vegetables (subgroup 1C); bulb vegetables (crop group 3); dried shelled peas and beans, except soybean (subgroup 6C); forage, fodder and straw of cereal grains (crop group 16); grass forage, fodder and hay (crop group 17); nongrass animal feeds (crop group 18); herbs and spices (crop group 19), and oil seeds (crop group 20).

Because a substantial proportion of the residue values for turnip roots, onions, wheat grain, and soybean seeds were <LOQ, the tolerance spreadsheet was not utilized to calculate possible tolerances for these commodities. Rather, the rotational crop tolerances for these representative commodities are based on the maximum observed residue values for turnips roots (0.023 ppm), onions (0.06 ppm), wheat grain (<0.077 ppm), and soybean seeds (0.59 ppm). Based on the residues in/on turnip roots, the current tolerance for root and tuber vegetables (crop group 1) should be changed to tuberous and corm vegetables (subgroup 1C) and reduced to 0.05 ppm. Based on the residues in onions, the current tolerances for bulb vegetables (crop group 3) can be lowered to 0.1 ppm. Based on the residues in soybean seeds, the current tolerance for legume vegetables (crop group 6) should be changed to dried and shelled peas and bean, except soybean (subgroup 6C) and increased to 1.0 ppm. The residue data on soybeans will also support a rotational crop tolerance at 1.0 ppm for oil seeds (crop group 20). As residues were <LOQ in/on

all samples of wheat grain following a 2x application to the primary crop, a rotational crop tolerance for cereal grains (crop group 15) is not necessary.

Because combined methoxyfenozide residues were >LOQ in all samples of wheat forage, hay and straw and in most samples (>87%) of soybean forage and hay, the Agency's *Guidance for Setting Pesticide Tolerance Based on Field Trial Data* was utilized for determining appropriate tolerance levels on these commodities (Appendix II). The calculated tolerances were 3.0 ppm for wheat forage, 4.5 ppm for wheat hay, 6.0 ppm for wheat straw, 4.5 ppm for soybean forage and 8.0 ppm for soybean hay.

Based on the calculated tolerances for wheat forage, hay and straw, the current tolerance for cereal grain forage, fodder and straw (crop group 16) should be lowered to 6.0 ppm. These wheat data will also support lowering the current tolerance for grasses (crop group 17) to 6.0 ppm. Based on the calculated tolerances for wheat forage and hay, the current tolerance for herbs and spices (crop group 19) can be lowered to 4.5 ppm. Although rotational crop tolerances for legume foliage is no longer necessary, the available soybean forage and hay data will support reducing the current tolerance on nongrass animal feeds (crop group 18) to 8.0 ppm.

Maximum residue limits (MRLs) for residues of methoxyfenozide have been established by Codex, Canada and Mexico on various plant and livestock (Canada and Codex) commodities. However, no Codex, Canadian or Mexican MRLs for methoxyfenozide have been proposed or established for the commodities being considered in this report. Therefore, there are no questions about compatibility of the recommended tolerances.

Table 9. Tolerance Summary for Methoxyfenozide.

Commodity	Established Tolerances (ppm)	Recommended Tolerance (ppm)	Comments; *Correct Commodity Definition*
40 CFR §180.544 (a)(1)			
Leafy greens, subgroup 4A	30	30	Based on all the available spinach field trial data, the calculated tolerance for spinach is 30 ppm, which is identical to the current subgroup tolerance.
Plum, prune, fresh	0.30	0.6	Based on all the available plum field trial data, the tolerance for plums should be increased to 0.6 ppm.
40 CFR §180.544 (d)(1)			
Vegetable, bulb, group 3	0.20	0.1	Tolerance should be reduced based on maximum residues of 0.06 ppm in onions.
Vegetable, root and tuber, group 1	0.10	0.05	Based on maximum residues of 0.023 ppm in turnip roots, the tolerance should be lowered to 0.05 ppm and changed to cover only *Vegetable, tuberous and corm, subgroup 1C.*
Vegetable, leaves of root an tuber, group 2	0.20	Delete	Covered by existing primary crop tolerance on leaves of root and tuber vegetables (group 2).

Table 9. Tolerance Summary for Methoxyfenozide.			
Commodity	Established Tolerances (ppm)	Recommended Tolerance (ppm)	Comments; *Correct Commodity Definition*
40 CFR §180.544 (d)(2)			
Vegetable, legume, group 6	0.1	1.0	Based on maximum combined residues of 0.59 ppm in soybean seed, the tolerance should be increased to 1.0 ppm and changed to cover only *Pea and bean, dried shelled, except soybean, subgroup 6C*
Vegetable, foliage of legume, group 7	10.0	Delete	Foliage of legumes covered by the existing primary crop tolerances on foliage of legume vegetables, except soybean, (subgroup 7A) and soybean forage and hay.
Grain, cereal, forage, fodder and straw, group 16	10.0	6.0	Based on the available rotational wheat field trials, the calculated tolerances are 3 ppm for forage, 4.5 ppm for hay and 6.0 ppm for straw.
Grass, forage, fodder and hay, group 17	10.0	6.0	Tolerance can be reduced to 6.0 ppm based on wheat forage, hay and straw residue data.
Animal feed, nongrass, group 18	10.0	8.0	Tolerance can be lowered to 8.0 ppm based on soybean forage and hay residue data.
Herb and spice, group 19	10.0	4.5	Tolerance can be reduced to 4.5 ppm based on wheat forage and hay residue data.
Oil seed, group 20	None	1.0	Tolerance should be established at 1.0 ppm based on soybean seed data.

References

DP#: 258034
Subject: PP#8F5004 & PP#8F5006; Methoxyfenozide. Conclusions of the 7/13/99 Meeting of the Metabolism Assessment Review Committee.
From: W. Wassell
To: G. Kramer
Dated: 23/JUL/1999
MRIDs: None

DP#s: 251225, 251218, 249458, and 249438
Subject: PP# 8F5004 & PP#8F5006: Methoxyfenozide on Cotton and the Pome Fruit Crop Group. Evaluation of Metabolism Data, Residue Data, and Analytical Methodology.
From: W. Wassell
To: S. Lewis/J. Tavano
Dated: 27/JUL/1999
MRIDs: 44617816-44617822, 44617825, 44617826, 44617828-44617832, 44626303-44626306, 44626308-44626312, 44689101, and 44689102.

DP#: 258155
Subject: PP#8F5004 & PP#8F5006 Methoxyfenozide in COTTON and the POME FRUIT Crop Group. Human Health Risk Assessment for New Reduced-Risk Insecticide.
From: W. Wassell
To: A. Layne/J. Tavano
Dated: 20/AUG/1999
MRIDs: None

DP#: 259989
Subject: PP9F06033: Section 3 Request for Use of Methoxyfenozide on Grapes and Fruiting Vegetables. Review of Analytical Methods and Residue Chemistry Data.
From: M. Doherty
To: A. Layne/J. Tavano
Dated: 08/AUG/2000
MRIDs: 44873405 through 44873411

DP#s: 269986, 274542
Subject: Methoxyfenozide in/on Various Rotational Crops. Residue Chemistry Review.
From: M. Nelson
To: M. Laws/J. Tavano
Dated: 07/AUG/2002
MRIDs: 45194701, 45194702, 45194703, 45194704

DP#: 269969
Subject: PP#0F06213: Methoxyfenozide in/on Field Corn and Sweet Corn; Poultry Tolerances; and, Higher Tolerances on Other Selected Animal Commodities. Residue Chemistry Review.
From: M. Nelson
To: M. Laws/J. Tavano
Dated: 07/AUG/2002
MRIDs: 45213500, 45213502 through 45213514

DP#: 260888
Subject: PP#9F06062: Methoxyfenozide in/on Leafy and Brassica Vegetables Crop Subgroups 4A, 4B, 5A and 5B. Residue Chemistry Review.
From: M. Nelson
To: M. Laws/J. Tavano
Dated: 07/AUG/2002
MRIDs: 44924302, 44924303, 44924304

DP#: 274516
Subject: PP#1F06259: Methoxyfenozide in/on Stone Fruit and Prunes. Residue Chemistry Summary Document Review.
From: M. Nelson
To: M. Laws/J. Tavano
Dated: 07/AUG/2002
MRIDs: 45313302, 45313303, 45313304

DP#: 259549
Subject: METHOXYFENOZIDE Supplemental Human Health Risk Assessment for: PP#9F06033 - Fruiting Vegetables (except Cucurbits) Crop Group; Grapes; Raisins; PP#9F06062 - Leafy and Cole (Brassica) Vegetables Crop Groups; PP#0F06201 - Rotational Crops; PP#0F06213 - Field and Sweet Corn; Higher Milk/Fat /Mbyp; Add Poultry/Eggs; PP#1F06259 - Stone Fruits Crop Group; Prune; PP#1F06287 - Tree Nuts Crop Group, including Pistachio; Almond Hulls; PP#2E06382 - Globe Artichoke; and PP#2E06408 - Lychee, including Longan, Spanish Lime, Pulasan, and Rambutan.
From: M. Nelson
To: M. Laws/J. Tavano/S Brothers/R. Forrest
Dated: 07/AUG/2002
MRIDs: None

Attachments:
Appendix I - International Residue Limit Status sheet
Appendix II - Tolerance Assessment Calculations

Appendix I - International Residue Limit Status Sheet

INTERNATIONAL RESIDUE LIMIT STATUS

Chemical Name: 3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide	Common Name: methoxyfenozide	□ Proposed tolerance √ Reevaluated tolerance □ Other	Date: 02/05/2008

Codex Status (Maximum Residue Limits)	**U. S. Tolerances**
□ No Codex proposal step 6 or above □No Codex proposal step 6 or above for the crops requested	Petition Number: NA DP Barcode: 322948 Other Identifier:
Residue definition (step 8/CXL): Methoxyfenozide	Reviewer/Branch: C. Swartz/J. Redden; RAB2/ARIA
	Residue definition: methoxyfenozide in all primary crops and high moisture rotational crops; combined residues of methoxyfenozide, RH-117,236, RH-151,055 and RH-152,072 in low-moisture rotational crops.

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
Lettuce, head	15	Leafy greens, subgroup 4A	30
Lettuce, leaf	30	Plum, prune, fresh	0.6
Maize fodder (dry)	60	Vegetable, bulb, group 3	0.1
Stone fruits	2	Vegetable, tuberous and corm, subgroup 1C	0.05
		Pea and bean, dried and shelled, except soybean, subgroup 6C	1.0
		Grain, cereal, forage, fodder and straw, group 16	6.0
		Grass, forage, fodder and hay, group 17	6.0
		Animal feed, nongrass, group 18	8.0
		Herb and spice, group 19	4.5
		Oil seed, group 20	1.0

Limits for Canada	**Limits for Mexico**
□ No Limits √No Limits for the crops requested	□No Limits √No Limits for the crops requested
Residue definition: plants: 3-methoxy-2-methylbenzoic acid, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide livestock: 3-methoxy-2-methylbenzoic acid, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide, including the metabolite β-D-glucopyranuronic acid, 3-{[2-(1,1-dimethylethyl)-2-(3,5-dimethylbenzoyl)-hydrazino]carbonyl}-2-methylphenyl-	Residue definition: methoxyfenozide

Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)

Notes/Special Instructions: S.Funk, 04/06/2009.

Appendix II – Tolerance Assessment Calculations

The datasets used to calculate tolerances for methoxyfenozide in spinach and plums consisted of field trial data representing application rates at 1x for spinach and essentially 1.2x of plums with PHIs of 1 day and 6-8 days, respectively. As specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP, the field trial application rates and PHIs are within 25% of the maximum label application rate and minimum label PHI, respectively. The residue values used to calculate the tolerances for spinach and plums are provided in Tables II-1 and II-2. Residues of methoxyfenozide were >LOQ (0.02 ppm) in all spinach and plum samples.

The entire datasets for spinach and plums were entered into the tolerance spreadsheet. Visual inspection of the lognormal probability plot (Figures II-1 and II-3) provided in the spreadsheet indicate that the datasets are reasonably lognormal. The results from the approximate Shapiro-Francia test statistic (Figures II-2 and II-4) confirmed that the assumption of lognormality should not be rejected. The calculated tolerances are 30 ppm for spinach and 0.6 ppm for plums.

The tolerance spreadsheet was not utilized for calculating possible rotational crop tolerances for cucumbers, tomatoes, onions, turnip tops and roots, wheat grain, and soybean seeds, residues were largely <LOQ in samples of these commodities. However, residue values in the datasets for wheat forage, hay and straw and soybean forage and hay were largely ≥LOQ (Tables II-3 and II-4); therefore, the Agency's *Guidance for Setting Pesticide Tolerance Based on Field Trial Data* was utilized for determining appropriate tolerance levels on these commodities.

The datasets for these rotational crop commodities were entered into the tolerance spreadsheet. Visual inspection of the lognormal probability plot (Figures II-5, -7, -9, -11, and -13) provided in the spreadsheet indicate that the datasets are reasonably lognormal. The results from the approximate Shapiro-Francia test statistic (Figures II-6, -8, -10, -12 and -14) confirmed that the assumption of lognormality should not be rejected for wheat forage, hay and straw and soybean hay, but should be rejected for soybean forage. The calculated tolerances were 3.0 ppm for wheat forage, 4.5 ppm for wheat hay, 6.0 ppm for wheat straw, 4.5 ppm for soybean forage and 8.0 ppm for soybean hay.

Table II-1. Residue data used to calculate tolerance for methoxyfenozide on spinach.		
Regulator:	EPA	
Chemical:	Methoxyfenozide	
Crop:	Spinach	
PHI:	1 day	
App. Rate:	1.00-1.03 lb ai/A	
Submitter:	Dow AgroSciences	
MRID Citation:	MRID 45870501	MRID 44924304
	Residues	
	5.40	9.68
	5.56	9.97
	6.64	10.30
	8.98	11.00
	9.26	12.80
	11.00	13.80
		16.40
		17.20
		17.30
		17.80

Figure II-1. Lognormal probability plot for residues of methoxyfenozide in/on spinach.

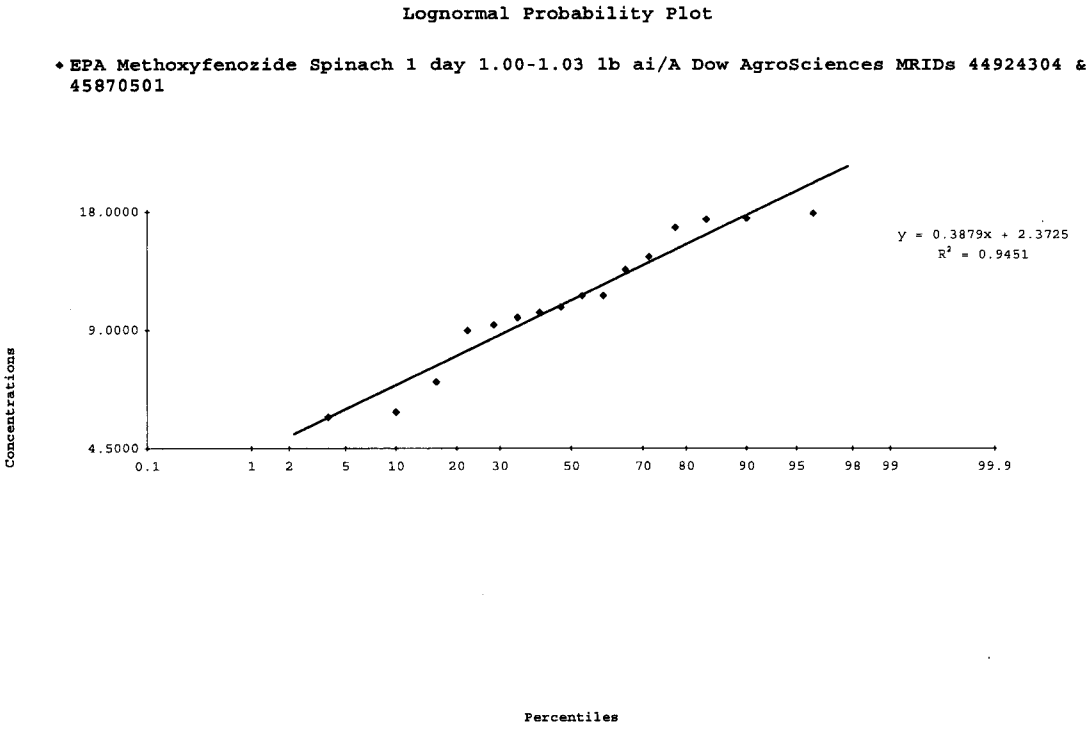


Figure II-2. Tolerance spreadsheet summary of methoxyfenozide field trial data for spinach.

Regulator:	EPA
Chemical:	Methoxyfenozide
Crop:	Spinach
PHI:	1 day
App. Rate:	1.00-1.03 lb ai/A
Submitter:	Dow AgroSciences
MRID Citation:	MRIDs 44924304 & 45870501
n:	16
min:	5.40
max:	17.80
median;	10.65
average:	11.44

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	19 (25)	25 (30)	25 (--)
EU Method I Log Normal	[redacted]	[redacted] (45)	35 (--)
EU Method II Distribution-Free	35		
California Method μ + 3σ	25		
UPLMedian95th	75		
Approximate Shapiro-Francia Normality Test	0.9451 p-value > 0.05 : Do not reject lognormality assumption		

Would you like the above values rounded? (Y or N) ==> Y

Table II-2. Residue data used to calculate tolerance for methoxyfenozide on plums.		
Regulator:	EPA	
Chemical:	Methoxyfenozide	
Crop:	Plums	
PHI:	6-8 days	
App. Rate:	0.99-1.07 lb ai/A	1.78-1.83 lb ai/A [1]
Submitter:	Dow AgroSciences	
MRID Citation:	MRID 46606301	MRID 45313304
	Residues	**Residues**
	0.14	0.322
	0.23	0.360
	0.35	0.287
	0.50	0.317
		0.107
		0.151
		0.099
		0.233
		0.187
		0.193
		0.146
		0.181
		0.124
		0.146

[1] Although total rate in the earlier field trials was 1.8x, the single use rate was 1.2x the labeled single rate. As the final 4 applications are likely to account for the majority of residues, the, earlier plum field trial data will not be corrected to a 1x level for tolerance assessment.

Figure II-3. Lognormal probability plot for residues of methoxyfenozide in/on plums.

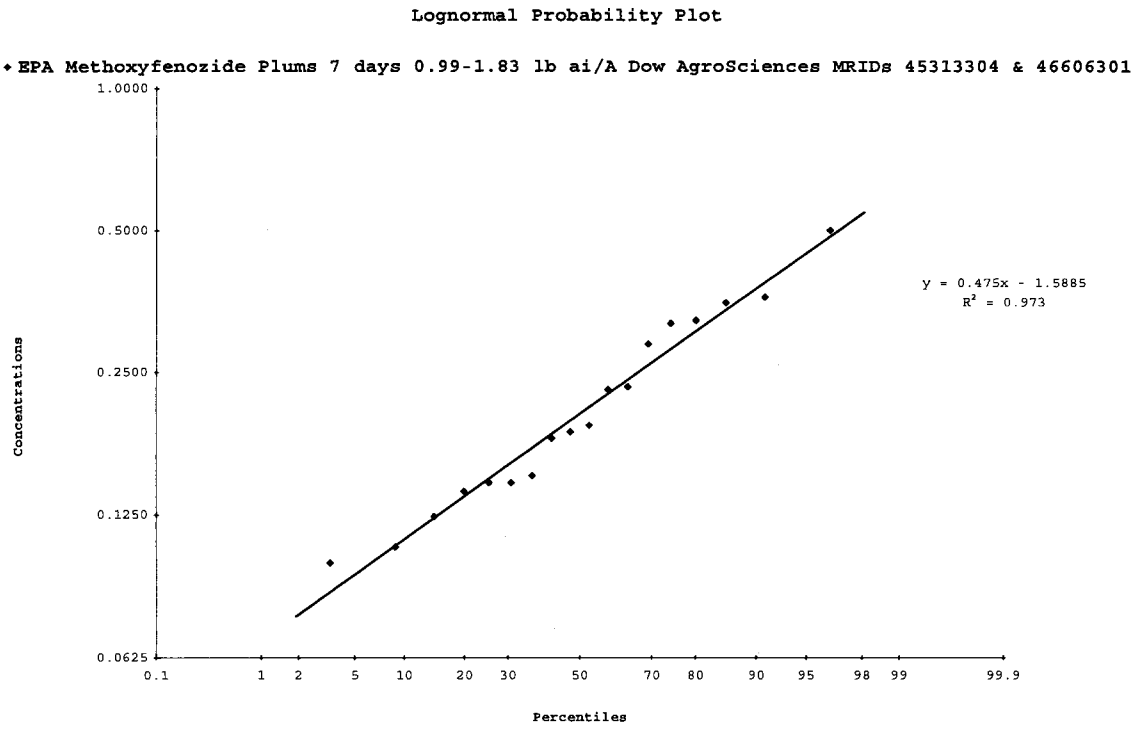


Figure II-4. Tolerance spreadsheet summary of methoxyfenozide field trial data for plums.

Regulator:	EPA
Chemical:	Methoxyfenozide
Crop:	Plums
PHI:	7 days
App. Rate:	0.99-1.83 lb ai/A
Submitter:	Dow AgroSciences
MRID Citation:	MRIDs 45313304 & 46606301
n:	18
min:	0.10
max:	0.50
median;	0.19
average:	0.23

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	0.45 (0.50)	0.50 (0.60)	0.60 (--)
EU Method I Log Normal	0.45 **(0.70)**	0.60 (1.0)	0.90 (--)
EU Method II Distribution-Free		0.70	
California Method μ + 3σ		**0.60**	
UPLMedian95th		**1.3**	
Approximate Shapiro-Francia Normality Test		0.9730 p-value > 0.05 : Do not reject lognormality assumption	

Would you like the above values rounded? (Y or N) ==> Y

Table II-3.	**Residue data used to calculate tolerance for combined methoxyfenozide on rotational wheat commodities.**			
Regulator:	EPA			
Chemical:	Methoxyfenozide			
Crop:	Wheat Forage	Wheat Hay	Wheat Straw	Wheat Grain
PHI:	~7-day plant-back interval			
App. Rate:	2.0 lb ai/A			
Submitter:	Dow AgroSciences			
MRID Citation:	MRIDs 45194704 and 45870502			
	Combined Residues (ppm) [1]			
	5.40	0.106	0.274	**0.077** [2]
	5.56	0.115	0.297	**0.077**
	6.64	0.265	0.395	**0.077**
	8.98	0.373	0.462	**0.077**
	9.26	0.394	0.476	**0.077**
	9.68	0.409	0.513	**0.077**
	9.97	0.498	0.523	**0.077**
	10.30	0.540	0.558	**0.077**
	11.00	0.616	0.643	**0.077**
	11.00	0.683	0.654	**0.077**
	12.80	0.721	0.760	**0.077**
	13.80	0.736	0.912	**0.077**
	16.40	0.748	1.494	**0.077**
	17.20	1.002	1.547	**0.077**
	17.30	1.033	2.086	**0.077**
	17.80	1.391	4.614	**0.077**

[1] Combined residues are expressed in parent equivalents. For combining residues, residues of RH-117,236 and RH-151,055 were converted to parent equivalents by multiplying by 1.04 and 0.715, respectively.

[2] The LOQ for combined residues is 0.077 ppm; residues <LOQ are listed and **bolded**.

Figure II-5. Lognormal probability plot methoxyfenozide residues in rotational wheat forage.

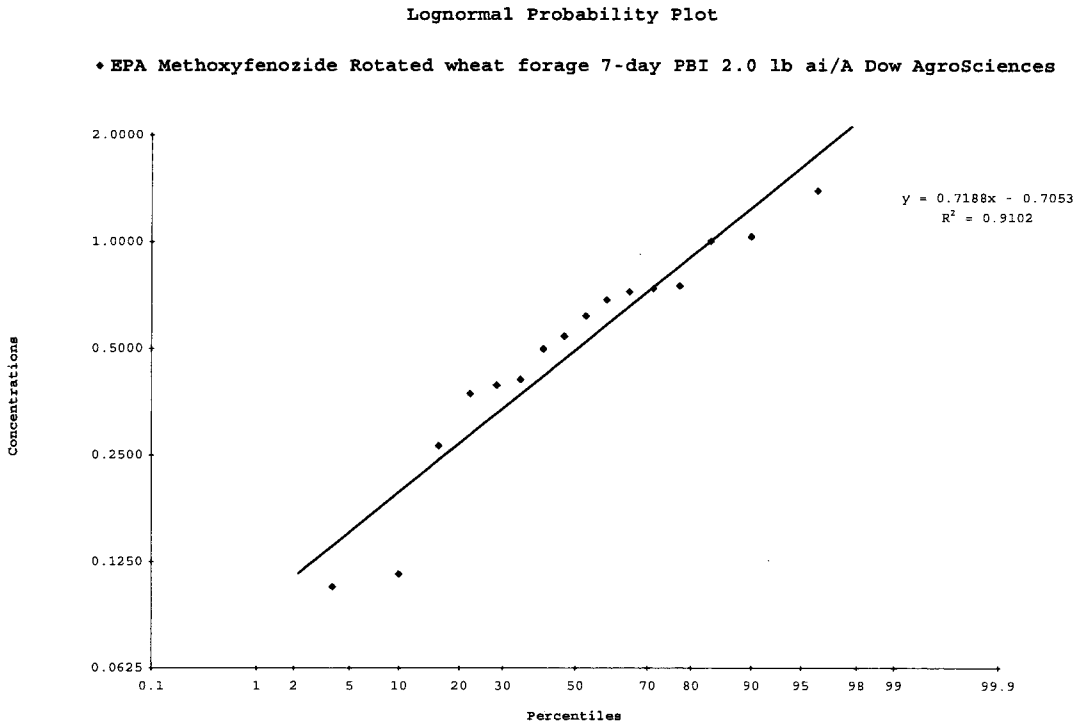


Figure II-6. Tolerance spreadsheet summary for combined methoxyfenozide residues in rotational wheat forage.

	Regulator: EPA Chemical: Methoxyfenozide Crop: Rotated wheat forage PHI: 7-day PBI App. Rate: 2.0 lb ai/A Submitter: Dow AgroSciences MRID Citation: n: 16 min: 0.11 max: 1.39 median: 0.58 average: 0.60		
	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	1.2 (1.5)	1.5 (1.8)	1.7 (--)
EU Method I Log Normal	1.7 (3.5)	3.0 (7.0)	5.0 (--)
EU Method II Distribution-Free	1.5		
California Method $\mu + 3\sigma$	1.7		
UPLMedian95th	4.0		
Approximate Shapiro-Francia Normality Test	0.9102 p-value > 0.05 : Do not reject lognormality assumption		

Would you like the above values rounded? (Y or N) ==> Y

Figure II-7. Lognormal probability plot for residues of methoxyfenozide in rotational wheat hay.

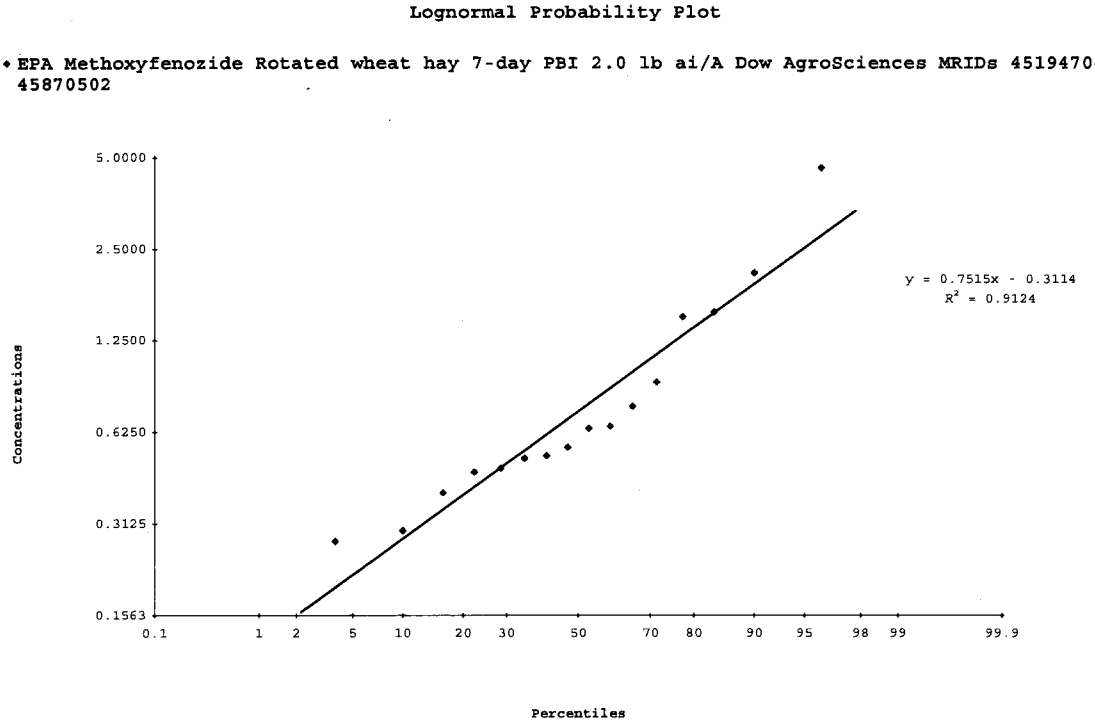


Figure II-8. Tolerance spreadsheet summary for methoxyfenozide residues in rotational wheat hay.

Regulator:	EPA
Chemical:	Methoxyfenozide
Crop:	Rotated wheat hay
PHI:	7-day PBI
App. Rate:	2.0 lb ai/A
Submitter:	Dow AgroSciences
MRID Citation:	MRIDs 45194704 & 45870502
n:	16
min:	0.27
max:	4.61
median;	0.60
average:	1.01

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	3.0 (4.0)	4.0 (5.0)	4.5 (--)
EU Method I Log Normal	3.0 (5.0)	[illegible] (10)	8.0 (--)
EU Method II Distribution-Free	3.0		
California Method μ + 3σ	4.5		
UPLMedian95th	4.0		
Approximate Shapiro-Francia Normality Test	0.9124 p-value > 0.05 : Do not reject lognormality assumption		

Would you like the above values rounded? (Y or N) ==> Y

Figure II-9. Lognormal probability plot for residues of methoxyfenozide in rotational wheat straw.

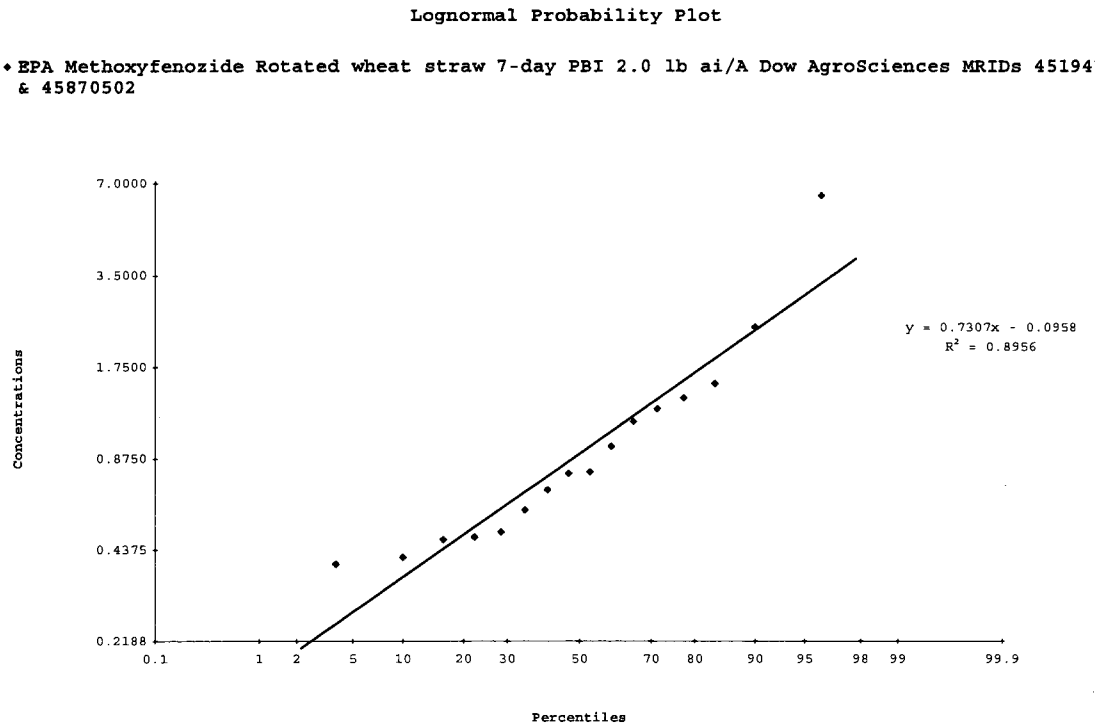


Figure II-10. Tolerance spreadsheet summary for methoxyfenozide residues in rotational wheat straw.

Regulator:	EPA
Chemical:	Methoxyfenozide
Crop:	Rotated wheat straw
PHI:	7-day PBI
App. Rate:	2.0 lb ai/A
Submitter:	Dow AgroSciences
MRID Citation:	MRIDs 45194704 & 45870502
n:	16
min:	0.39
max:	6.39
median;	0.79
average:	1.26

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	4.0 (5.0)	5.0 (7.0)	6.0 (--)
EU Method I Log Normal	(8.0)	6.0 (12)	9.0 (--)
EU Method II Distribution-Free	3.0		
California Method $\mu + 3\sigma$	6.0		
UPLMedian95th	6.0		
Approximate Shapiro-Francia Normality Test	0.8956 p-value > 0.05 : Do not reject lognormality assumption		

Would you like the above values rounded? (Y or N)==> Y

Table II-4. Residue data used to calculate tolerance for Methoxyfenozide on Rotational Soybean Commodities.			
Regulator:	EPA		
Chemical:	Methoxyfenozide		
Crop:	Soybean Forage	Soybean Hay	Soybean Seed
PHI:	~7-day plant-back interval		
App. Rate:	2.0 lb ai/A		
Submitter:	Dow AgroSciences		
MRID Citation:	MRID 45870502		
	Combined Residues of Methoxyfenozide (ppm)		
	0.077	**0.077**	**0.077**
	0.077	**0.077**	**0.077**
	0.136	0.202	**0.077**
	0.154	0.241	**0.077**
	0.173	0.342	**0.077**
	0.179	0.348	**0.077**
	0.208	0.446	**0.077**
	0.211	0.448	**0.077**
	0.231	0.501	**0.077**
	0.334	0.617	**0.077**
	0.343	0.619	**0.077**
	0.359	0.686	**0.077**
	0.697	0.713	**0.077**
	0.721	0.738	0.089
	3.214	3.648	0.355
	4.284	7.105	0.590

[1] Combined residues are expressed in parent equivalents. For combining residues, residues of RH-117,236 and RH-151,055 were converted to parent equivalents by multiplying by 1.04 and 0.715, respectively.

[2] The LOQ for combined residues is 0.077 ppm; residues <LOQ are listed and **bolded**.

Figure II-11. Lognormal probability plot for residues of methoxyfenozide in rotational soybean forage.

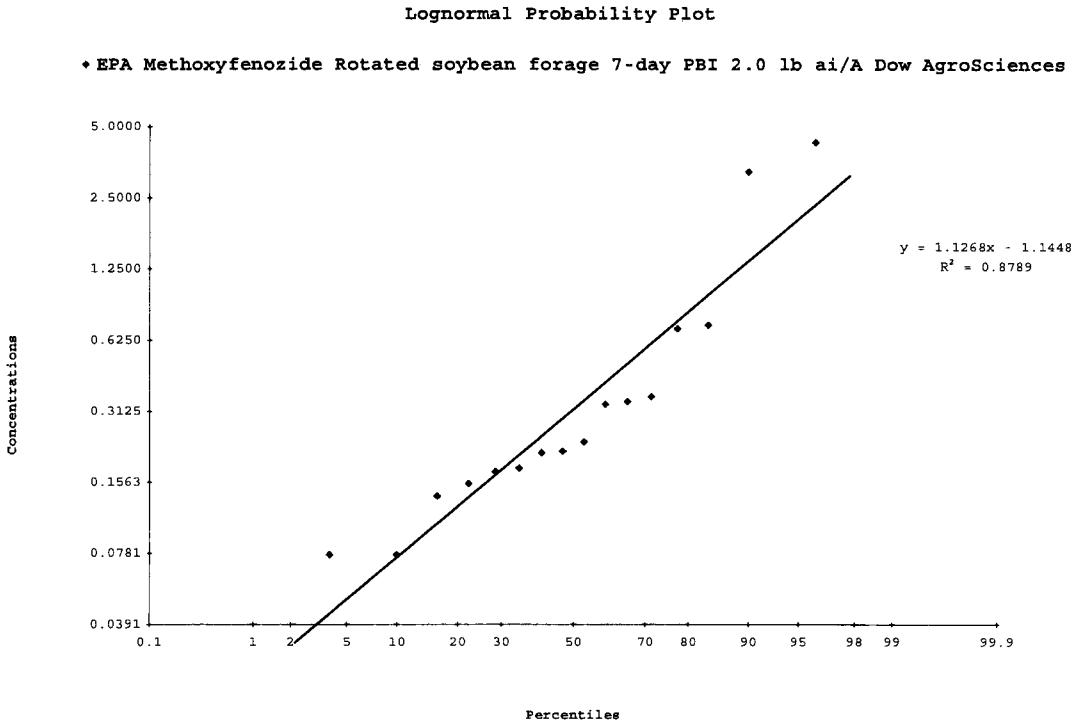


Figure II-12. Tolerance spreadsheet summary for residues of methoxyfenozide in rotational soybean forage.

Regulator:	EPA
Chemical:	Methoxyfenozide
Crop:	tated soybean forage
PHI:	7-day PBI
App. Rate:	2.0 lb ai/A
Submitter:	Dow AgroSciences
MRID Citation:	
n:	16
min:	0.08
max:	4.28
median;	0.22
average:	0.71

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	3.0 (4.0)	4.0 (5.0)	4.5 (--)
EU Method I Log Normal	2.5 (6.0)	5.0 (18)	12 (--)
EU Method II Distribution-Free		1.3	
California Method μ + 3σ		[redacted]	
UPLMedian95th		1.5	
Approximate Shapiro-Francia Normality Test	0.8789 0.05 >= p-value > 0.01 : Reject lognormality assumption		

Would you like the above values rounded? (Y or N)==> Y

Figure II-13. Lognormal probability plot for residues of methoxyfenozide in rotational soybean hay.

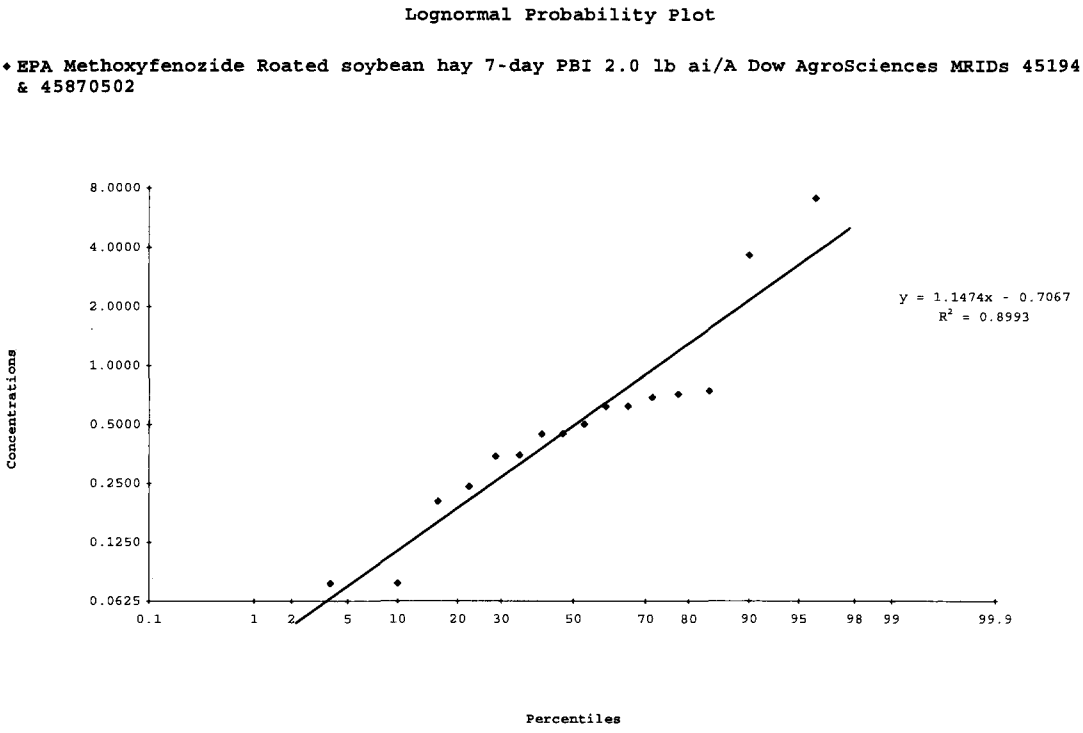


Figure II-14. Tolerance spreadsheet summary for residues of methoxyfenozide in rotational soybean hay.

Regulator:	EPA
Chemical:	Methoxyfenozide
Crop:	Roated soybean hay
PHI:	7-day PBI
App. Rate:	2.0 lb ai/A
Submitter:	Dow AgroSciences
MRID Citation:	MRIDs 45194704 & 45870502
n:	16
min:	0.08
max:	7.11
median;	0.47
average:	1.05

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	4.5 (6.0)	6.0 (8.0)	7.0 (--)
EU Method I Log Normal	3.5 (10)	5.0 (30)	18 (--)
EU Method II Distribution-Free	1.5		
California Method $\mu + 3\sigma$	7.0		
UPLMedian95th	3.5		
Approximate Shapiro-Francia Normality Test	0.8993 p-value > 0.05 : Do not reject lognormality assumption		

Would you like the above values rounded? (Y or N)==> Y

Methoxyfenozide/121027/Dow AgroSciences
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial – Spinach

Primary Evaluator Debra Rate, Ph.D., Biologist Date: 07/APR/2009
Alterntive Risk Integration and Assessment (ARIA)
Risk Integration, Minor Use, and Emergency Response
Branch (RIMUERB) / Registration Division (RD; 7505P)

Approved by William Cutchin, Acting Senior Branch Scientist
ARIA/RIMUERB/RD (7505P)

This DER was originally prepared under contract by Dynamac Corporation (submitted 31/JAN/2008). The DER has been reviewed by ARIA and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

MRID No. 45870501. R. S. Kludas (2003) RH-2485 (methoxyfenozide) 80W Field Residue Studies for Spinach of the Leafy Vegetables Crop Grouping. Supplement to TR 34-99-75 "RH-2485 80W and 2F Field Residue Studies for the Leafy Vegetables Crop Grouping": Lab Project Number: 34P-99-37. Study No.34-01-22 Unpublished study prepared by Dow AgroSciences. 247 pages.

EXECUTIVE SUMMARY:

Dow AgroSciences submitted supplemental spinach field trial data for methoxyfenozide. In 3 field trials conducted during 1999-2000 in EPA growing Regions 1, 2, and 10, a 80% wettable powder (WP) formulation of methoxyfenozide was applied to spinach as four broadcast foliar applications during vegetative development at 0.25-0.26 lb ai/A/application at retreatment intervals (RTIs) of 7-10 days, for a total of 1.00-1.03 lb ai/A. Applications were made using ground equipment at volumes of 16-46 gal/A, and included the use of a non-ionic surfactant (NIS). Single control and duplicate treated samples of spinach were harvested from each field trial 1 day after treatment (DAT), and additional samples were collected from one test at 0, 3, 7 and 10 DAT to assess residue decline. Samples were stored frozen for up to 13 months prior to extraction for analysis, an interval supported by the available storage stability data. The number and geographical representation of the submitted field trials adequately addresses the conditional data request.

The high performance liquid chromatography with ultra violet detection (HPLC/UV) method (TR 34-99-74) used to determine residues of methoxyfenozide in/on spinach was adequately validated in conjunction with the analysis of field trial samples. Methoxyfenozide residues are extracted with acidic methanol and purified by liquid-liquid partitioning and elution through a basic alumina column and an Envicarb solid phase extraction (SPE) cartridge. Residues were then determined by HPLC/UV using external standards. The validated limit of quantitation (LOQ) is 0.020 ppm in spinach, and the limit of detection (LOD) is 0.006 ppm.

Following four broadcast foliar applications of methoxyfenozide (WP) totaling 1.00-1.03 lb ai/A, residues of methoxyfenozide were 5.4-11.0 ppm in/on 6 samples of spinach harvested at 1 DAT. Average residues at 1 DAT were 7.81 ppm and the highest average field trial (HAFT) residues were 9.99 ppm. Data from the residues decline test showed that average methoxyfenozide residues were relatively unchanged from 0 to 10 DAT.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the supplemental spinach field trial data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 322948.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Methoxyfenozide is a diacylhydrazine insecticide used on a variety of crops for control of armyworms and other lepidopterous pest species. Methoxyfenozide mimics the action of the molting hormone of lepidopterous larvae, causing the larvae to undergo an incomplete and premature molt, which ultimately results in their death. Methoxyfenozide is currently registered to Dow AgroSciences for use on a variety of crops. Permanent tolerances are established for methoxyfenozide *per se* on a wide variety of plant commodities at levels ranging from 0.05 ppm in/on field corn grain and sweet corn ears to 160 ppm in/on soybean aspirated grain fractions [40 CFR §180.544(a)(1)].

As a condition of registration for use on leafy vegetables (except *Brassica*), the Agency required three additional field trials on spinach in EPA growing Regions 1, 2, and 10 (DP# 260888, M. Nelson, 07/AUG/2002). Dow AgroSciences has submitted the current spinach field trials in response to this requirement. The nomenclature and physicochemical properties of methoxyfenozide are presented below in Tables A.1 and A.2.

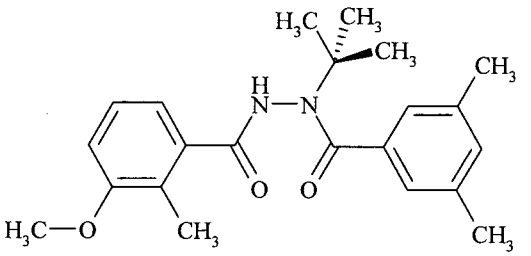
Table A.1. Methoxyfenozide Nomenclature.	
Chemical structure	
Common name	Methoxyfenozide
Company experimental name	RH-2485
IUPAC name	N-*tert*-butyl-N′-(3-methoxy-*o*-toluoyl)-3,5-xylohydrazide
CAS name	3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide
CAS registry number	161050-58-4
End-use product (EP)	80% WP (Intrepid 80WSP; EPA Reg., No 62719-438)

Table A.2. Physicochemical Properties of Methoxyfenozide.		
Parameter	Value	Reference
Melting point/range	206.1-208°C	DP# 231303, H. Podall, 19/MAY/1997
pH	7.0	
Density	0.740 ± 0.0081 g.cm^3	
Water solubility (mg/L at 20°C)	3.3	
Solvent solubility (g/L at 20°C)	N-heptane 1.87 Xylene 3.38 1,2-dichloroethane 36.72 Methanol 192.92 2-Propanol 50.22	
Vapor pressure at 25°C	1.33 x 10^{-5} Pa	
Dissociation constant, pK_a	None	
Octanol/water partition coefficient, Log(K_{OW})	3.72 ± 0.04	
UV/visible absorption spectrum	No absorption expected at λ> 300 nm	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Three spinach field trials were conducted in EPA growing Regions 1, 2, and 10 during 1999-2000 (Tables B.1.1 and B.1.2). In each field trial, methoxyfenozide (80% WP) was applied to spinach during vegetative development as four broadcast foliar applications at 0.25-0.26 lb ai/A/application at RTIs of 7-10 days, for a total of 1.00-1.03 lb ai/A/crop. Applications were made using ground equipment at volumes of 16-46 gal/A, and included the use of a non-ionic surfactant at 0.125-0.20% v/v.

TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State; Year)	Soil characteristics[1]			
	Type	%OM	pH	CEC (meq/g)
Germansville, PA 2000	Clay Loam	2.9	6.3	11.0
Athens, GA 2000	Sandy Clay Loam	1.4	5.9	7.9
Poplar, CA 2000	Sandy Loam	1.4	8.2	18.4

[1]These parameters are optional except in cases where their value affects the use pattern for the chemical.

Detailed climatological data were not provided, but general summaries of weather conditions during the field trials were reported for each site. No usual weather conditions were noted. The tests were conducted according to normal agricultural practices for the regions, and information was provided on the maintenance pesticides and fertilizers used at each site.

TABLE B.1.2. Study Use Pattern.

Location (City, State; Year) Trial ID	End-use product	Application Information					Tank Mix/ Adjuvants [2]
		Method; Timing	Volume (gal/A)	Single Rate (lb ai/A)	RTI [1] (days)	Total Rate (lb ai/A)	
Germansville, PA 2000 048	80% WP	Four broadcast foliar applications, at crop heights of 2-3", 3.5", 6" and 6-8"	40-46	0.25-0.26	8, 10, 7	1.03	Latron CS-7 0.19%
Athens, GA 2000 049	80% WP	Four broadcast foliar applications, at crop heights of 1.5", 2", 5",and 7"	28-31	0.25	8	1.00	Latron CS-7 0.19%
Poplar, CA 2000 002	80% WP	Four broadcast foliar applications, at crop heights of 6-8", 8-10", 12"	16-18	0.25-0.26	7	1.02	Latron CS-7 0.125%

[1] RTI = Retreatment Interval.
[2] This adjuvant is a NIS.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones	Spinach	
	Submitted	Requested
		U.S.
1	1	1
2	1	1
3	--	--
4	--	--
5	--	--
6	--	--
7	--	1
8	--	--
9	--	1
10	1	2
11	--	--
12	--	--
13	--	--
Total	3[1]	6[2]

[1] Three adequate spinach field trails in EPA growing Regions 6, 9 and 10 were previously reviewed (DP# 260888, M. Nelson, 07/AUG/2002).

[2] Number of tests required in conjunction with a crop group tolerance on leafy greens.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of spinach (≥2.5 lb/sample) were harvested from each field trial at 1 DAT, and additional samples were collected from one field trial at 0, 3, 7 and 10 DAT to assess residue decline. Samples were placed within frozen storage within 49 minutes of harvest, stored frozen at the field sites for 17-32 days, and then shipped frozen by ACDS freezer truck to Rohm and Haas Company, Springhouse, PA. Samples were chopped with dry ice and stored at <-4°C at the analytical laboratory until analysis.

B.3. Analytical Methodology

Samples of spinach were analyzed for residues of methoxyfenozide using the same HPLC/UV method (Report No. 34-99-74) that was utilized in the earlier spinach field trials (DP# 260888, M. Nelson, 07AUG/2002).

Residues were extracted with acidic methanol and initially purified by liquid-liquid partitioning with hexane and methylene chloride to remove non-polar compounds. Residues were then concentrated and purified using a basic alumina column and an Envicarb (carbon) solid phase extraction (SPE) cartridge. Residues in the final eluate were determined by HPLC/UV using external standards. The LOQ is 0.020 ppm and the LOD is 0.006 ppm.

The above method was validated in conjunction with the analysis of field trial samples, using control samples of spinach fortified with methoxyfenozide at 0.02, 0.10 and 1.0 ppm.

C. RESULTS AND DISCUSSION

The HPLC/UV method (TR 34-99-74) used for determining residues of methoxyfenozide in/on spinach was adequately validated in conjunction with the analysis of field trial samples. The average method recovery of methoxyfenozide was 91% with a standard deviation of 10% (Table C.1), excluding a single 25% recovery which was likely due to a fortification error. Apparent residues of methoxyfenozide were <LOQ in/on all control samples. Adequate sample calculations and example chromatograms were provided. Unfortunately, fortification levels used for the concurrent recoveries did not bracket residue levels. However, in an earlier independent laboratory validation, this method was validated at 0.02 ppm and 20 ppm in celery.

Spinach samples were stored frozen for up to 13 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating methoxyfenozide is stable under frozen conditions for up 12 months in head lettuce (DP# 269986, M. Nelson, 07/AUG/2002). These data support the storage intervals and conditions incurred by the field trial samples.

Following four broadcast foliar applications of methoxyfenozide (WP) totaling 1.00-1.03 lb ai/A, residues of methoxyfenozide were 5.40-11.00 ppm in/on 6 samples of spinach harvested at 1 DAT (Table C.3). Average residues were 7.81 ppm at 1 DAT and the HAFT residues were 9.99 ppm (Table C.4). In the residue decline test, average residues of methoxyfenozide were relatively unchanged from 0 to 10 DAT (Figure C.1).

Common cultural practices were used to maintain plants, and the weather conditions and maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Concurrent Recoveries of Methoxyfenozide from Spinach.

Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean ± Std. Dev. (%)
Spinach	0.02	8	80, 60, 85, 85, 90, 95, 80, 25 [1]	82 ± 11
	0.1	7	92, 90, 97, 91, 97, 95, 79	92 ± 6
	1.0	7	106, 94, 101, 97, 102, 101, 86	98 ± 7
	Total	**22**	**60-106**	**91 ± 10**

[1] Not included as this value is considered to be an outlier.

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration (months)[1]	Interval of Demonstrated Storage Stability (months)[2]
Spinach	-23 to -4	6-13	12

[1] Duration from harvest to extraction.
[2] Residues of methoxyfenozide are stable in frozen head lettuce for up to 12 months (DP# D269986, M. Nelson, 8/07/2002).

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TABLE C.3. Residue Data from Spinach Field Trials with Methoxyfenozide (WP).

Trial ID (City, State; Year)	EPA growing Region	Variety	Total Rate (lb ai/A)	PHI (days)	Residues (ppm) [1]	
Germansville, PA 2000 048	1	Tyee	1.03	1	8.98	11.0
Athens, GA 2000 049	2	Bloomsdale	1.00	1	5.40	5.56
Poplar, CA 2000 002	10	Polka	1.02	0	9.94	7.34
				1	9.26	6.64
				3	9.32	11.1
				7	8.06	5.52
				10	5.72	10.2

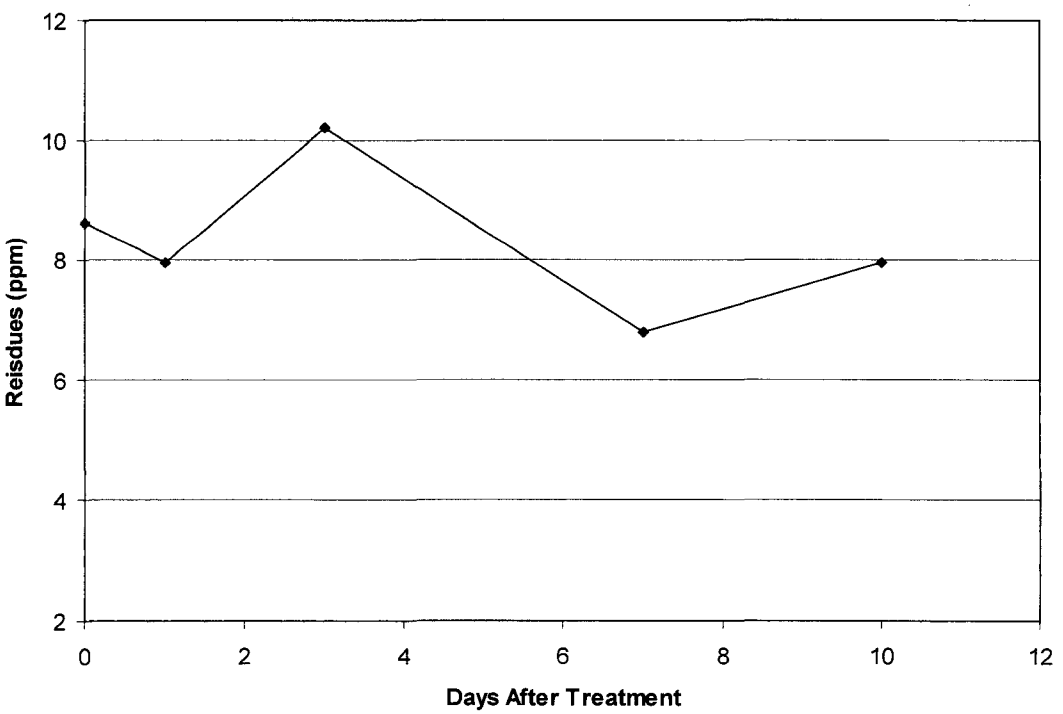
[1] The LOQ and LOD are 0.02 ppm and 0.006 ppm, respectively.

TABLE C.4. Summary of Residue Data from Spinach Field Trials with Methoxyfenozide (WP).

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm) [1]						
			n	Min.	Max.	HAFT [2]	Median	Mean	Std. Dev.
Spinach	1.00-1.03	1	6	5.40	11.0	9.99	7.81	7.81	2.28

[1] The validated LOQ is 0.02 ppm.
[2] HAFT = Highest Average Field Trial.

Figure C.1. Average Methoxyfenozide Residues in/on Spinach Over Time.



D. CONCLUSION

The supplemental spinach field trial data are adequate and support the use of methoxyfenozide (WP) on spinach as up to four broadcast foliar applications during vegetative development at up to 0.25 lb ai/A/application, for a maximum of 1.0 lb ai/A/season. The data support a minimum RTI of 7 days, a PHI of 1 day, and the use of a NIS as an adjuvant.

E. REFERENCES

DP#:	260888
Subject:	PP# 9F06062: Methoxyfenozide in/on Leafy and *Brassica* Vegetables Crop Subgroups 4A, 4B, 5A, and 5B. Residue Chemistry Review.
From:	M. Nelson
To:	M. Laws and J. Tavano
Dated:	07/AUG/2002
MRIDs:	44924302, 44924303, 44924304

DP#:	269986, D274542
Subject:	PP# 0F06201: Methoxyfenozide in/on Various Rotational Crops. Residue Chemistry Review.
From:	M. Nelson
To:	M. Laws and J. Tavano
Dated:	07/AUG/2002
MRIDs:	45194701, 45194702, 45194703, 45194704

F. DOCUMENT TRACKING

RDI: DNR (07/APR/2009); WC (27/APR/2009)
Petition Number: 9F06062
DP number: 322948
PC Code: 121207

Template Version June 2005

Methoxyfenozide/121027/Dow AgroSciences
DACO 7.4.4/OPPTS 860.1900/OECD IIA 6.6.3, 6.8.7 and IIIA 8.6
Field Accumulation in Rotational Crops – Representative Rotational Crops

Primary Evaluator Debra Rate, Ph.D., Biologist Date: 07/APR/2009
Alterntive Risk Integration and Assessment (ARIA)
Risk Integration, Minor Use, and Emergency Response
Branch (RIMUERB) / Registration Division (RD; 7505P)

Approved by William Cutchin, Acting Senior Branch Scientist
ARIA/RIMUERB/RD (7505P)

This DER was originally prepared under contract by Dynamac Corporation (submitted 31/JAN/2008). The DER has been reviewed by ARIA and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

MRID No. 45870502 Barney, W. (2003) RH-2485 80W Field Accumulation Study in Wheat, Soybean, Turnip, Cucumber, Mustard Greens, Tomato and Onion Rotational Crops: Lab Project Number: 34P-00-05: 21800011: 21800012. Unpublished study prepared by Grayson Research, LLC and SFBC Analytical Laboratories Inc. 850 p.

EXECUTIVE SUMMARY:

Dow AgroSciences submitted 12 field rotational crop trials conducted in EPA growing Regions 2, 4, 5, 7, 8, and 11 during 2000. At each field trial site, methoxyfenozide, formulated as an 80% wettable powder (WP) was applied to a primary crop of leaf lettuce as five broadcast foliar applications during vegetative development at rates of 0.39-0.41 lb ai/A/application and retreatment intervals (RTIs) of 7-10 days, for a total of 1.99-2.02 lb ai/A. Applications were made using ground equipment at volumes of 10-32 gal/A, and include the use of a non-ionic surfactant at 0.18-0.25% of the spray volume. The primary lettuce crop was harvested 1-3 days after the final application, and the representative rotational crops of soybeans, wheat, green onions, cucumbers, mustard greens, tomatoes and turnips were planted 6-10 days after the last application (~7-day plant-back interval, PBI). The numbers of field sites planted with each crop were as follows: 6 sites each for soybeans and wheat, 4 sites for turnips, 3 sites for mustard greens, 2 sites each for cucumbers and tomatoes, and 1 site for green onions. Geographic representation of the rotational crop was adequate. The rotational crops were grown according to standard agricultural practices, and harvested at the appropriate stage of maturity.

Single control and duplicate treated samples of each raw agricultural commodity (RAC) were collected at normal maturity; 89-270 days after planting (DAP) for wheat forage, 138-307 DAP for wheat hay, 161-339 DAP for wheat grain and straw, 38-60 DAP for soybean forage, 58-105 DAP for soybean hay, 103-146 DAP for soybean seed, 47-112 DAP for turnip tops and roots, 41-112 DAP for mustard greens, 51-62 DAP for cucumber, 45-107 DAP for tomato, and 70 DAP for green onions. Samples were stored frozen for up to 17.1 months prior to analysis, an interval supported by available storage stability data.

Residues of methoxyfenozide and its regulated metabolites in high- and low-moisture rotational crops were determined using a high performance liquid chromatography with ultra violet detection (HPLC/UV) or mass spectrometry (MS) method (Method TR 34-00-41), which is the current tolerance enforcement method for rotational crops. The method was adequately validated in conjunction with the analysis of field trial samples. Residues of methoxyfenozide in high-moisture crops were extracted with acidic MeOH/water, partitioned with hexane and methylene chloride (MDC), concentrated and cleaned up using a basic alumina column and an ENVI-CARB (carbon) solid phase extraction (SPE) cartridge. Methoxyfenozide residues were then determined by HPLC/UV, with confirmation by HPLC/MS. The validated limit of quantitation (LOQ) for methoxyfenozide in high-moisture crops is 0.02 ppm, and the reported limit of detection (LOD) is 0.006 ppm.

Residues in low-moisture crops were extracted with methanol/water and initially purified and separated by liquid-liquid partitioning into methanol/water and MDC/hexane fractions. Residues of parent and RH-117,236 in the MDC/hexane fraction were cleaned up using a Florisil column and an ENVI-CARB SPE cartridge, and then determined by HPLC/MS. Residues of RH-152,072 and RH-151,055 in methanol/water fraction were heated for 3 hours to remove the methanol and convert RH-152,072 to RH-151,055. The resulting residues of RH-151,055 were then purified by elution through C-18 and ENI-CARB SPE cartridges, and determined by HPLC/MS. The validated LOQ for methoxyfenozide and RH-117,236 in low-moisture crops is 0.02 ppm, and the LOD is 0.006 ppm. The validated method LOQ for RH-151,055 in low-moisture crops is 0.05 ppm, and the LOD is 0.015 ppm. For reporting combined residues, residues of RH-117,236 and RH-151,055 were converted to parent equivalents by multiplying by 1.04 and 0.715, respectively.

Residues of methoxyfenozide *per se* were <LOQ (<0.02 ppm) in all samples of wheat forage and grain, soybean seeds, turnip roots, tomatoes and cucumbers. Methoxyfenozide residues were <0.02-0.022 ppm in wheat hay, <0.02-0.023 ppm in wheat straw, <0.02-0.077 in soybean forage, <0.02-0.136 ppm in soybean hay, <0.03-0.038 ppm in turnip tops, <0.02-0.031 ppm in mustard greens and 0.028-0.060 ppm in green onions. Average residues of parent were 0.02 ppm in wheat forage, hay, straw and grain, as well as, soybean seeds, turnip roots, cucumber and tomato. Average parent residues were 0.044 ppm in soybean forage and green onions, 0.064 ppm in soybean hay, and 0.022 ppm in turnip tops and mustard greens.

In the low-moisture crops (wheat and soybean), substantial amounts of both the phenol metabolite (RH-117,236) and the sugar conjugates (RH-151,055 + RH-152,072) were detected in each commodity except wheat grain. Maximum residues of RH-117,236 were 0.038 ppm in wheat forage, 0.510 ppm in wheat hay, 0.841 ppm in wheat straw, 0.058 ppm in soybean forage, and 0.218 ppm in soybean hay. Maximum residues of RH-151,055/RH-152,072 were 1.318 ppm in wheat forage, 0.857 ppm in wheat hay, 0.845 ppm in wheat straw, 0.376 ppm in soybean forage, 0.907 ppm in soybean hay, and 0.768 ppm in soybean seeds.

In the low-moisture crops, combined residues of methoxyfenozide, RH-117,236 and RH-151,055/RH-152,072 (expressed in parent equivalents) were 0.106-1.002 ppm in wheat forage, 0.274-0.912 ppm in wheat hay, <LOQ (<0.077 ppm) in wheat grain, 0.329-1.278 ppm in wheat

straw, <0.077-0.359 ppm in soybean forage, <0.077-0.738 ppm in soybean hay, and <0.077-0.590 ppm in soybean seed. Average combined residues were 0.481 ppm in wheat forage, 0.539 ppm in wheat hay, <0.077 ppm in wheat grain, 0.710 ppm in wheat straw, 0.207 ppm in soybean forage, 0.468 ppm for soybean hay, and 0.143 ppm for soybean seed.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the data depicting cyproconazole residues in rotational crops are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 322948.

COMPLIANCE:

Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided, but lacked a signature and date. The following deviations from GLP were noted:

1. Cultural practices and applications of maintenance tèrtilizers and pesticides were not conducted under GLP Standards at all of the field trial sites. Irrigation records at field trials 21800011. 21800012. 21800013, 21800021 and 21800022 were not collected under GLP Standards.
2. In-life and historical weather data were not collected under GLP Standards at all of the field trial sites.
3. Crop and pesticide history data were not collected under GLP Standards at all of the field trial sites.
4. Soil characterization analyses were not conducted under GLP Standards.
5. The scales used to weigh samples were not maintained under GLP Standards at field trials 21800012. 21800014, 21800015, 21800018, 21900019 and 21800021.
6. Photographs from trial 21800017 were not produced under GLP Standards.
7. The pH meter used in trial 21800011 was not maintained under GLP Standards.
8. Measuring devices such as tape measures, graduated cylinders and pipettes used in field trial 21800015 were not maintained under GLP Standards.
9. Some data were not recorded or corrected in complete compliance with 40 CFR 160.130 (e).

None of the deviations from regulatory requirements reported had an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Methoxyfenozide is a diacylhydrazine insecticide used on a variety of crops for control of armyworms and other lepidopterous pest species. Methoxyfenozide mimics the action of the molting hormone of lepidopterous larvae, causing the larvae to undergo an incomplete and premature molt, which ultimately results in their death. Methoxyfenozide is currently registered to Dow AgroSciences.

Permanent tolerances are established for methoxyfenozide *per se* on a wide variety of plant commodities at levels ranging from 0.05 ppm in/on field corn grain and sweet corn ears to 160 ppm in/on soybean aspirated grain fractions [40 CFR §180.544(a)(1)]. Time limited tolerances have also been established for indirect or inadvertent residues in/on rotational crops. Rotational crop tolerances have been established for methoxyfenozide *per se* in/on bulb vegetables and root and tuber vegetables [40 CFR §180.544(d)(1)], and rotational crop tolerances have been established for the combined residues of methoxyfenozide, RH-117236, RH-155,055, and RH-152,072 in/on grasses, non-grass animal feeds, cereal grain forage, fodder and straw, legume vegetables, and herbs and spices [40 CFR §180.544(d)(2)].

As a condition for registration for methoxyfenozide, the Agency has required extensive rotational crop field trials (DP# 269986, M. Nelson, 07/AUG/2002). Dow AgroSciences has submitted the field rotational crop trials on a variety of crops in response to this requirement. The nomenclature of methoxyfenozide and its regulated metabolites is presented in Table A.1, and the physicochemical properties of methoxyfenozide are listed in Table A.2.

Table A.1. Nomenclature of Methoxyfenozide and its Regulated Metabolites.

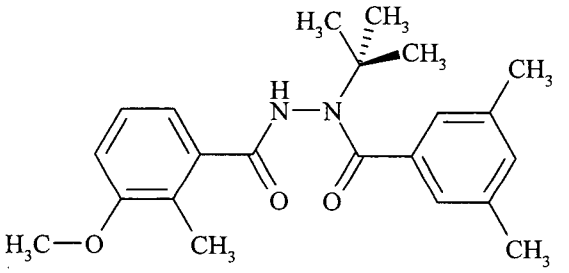
Chemical structure	
Common name	Methoxyfenozide
Company experimental name	RH-2485, RH-112,485
IUPAC name	N-*tert*-butyl-N′-(3-methoxy-*o*-toluoyl)-3,5-xylohydrazide
CAS name	3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide
CAS registry number	161050-58-4
End-use product (EP)	80% WP (Intrepid 80WSP; EPA Reg., No 62719-438)

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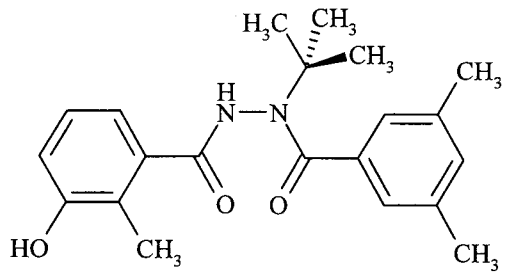
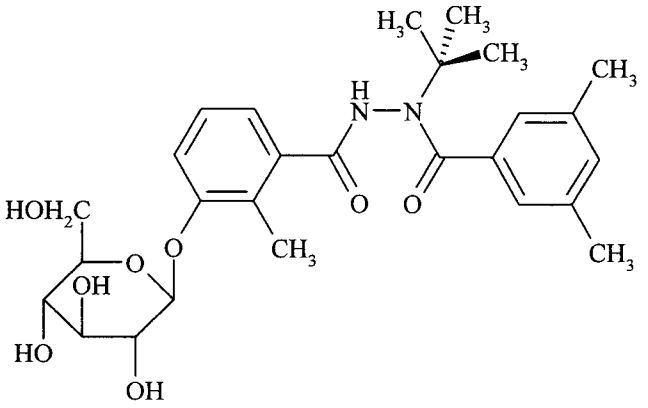
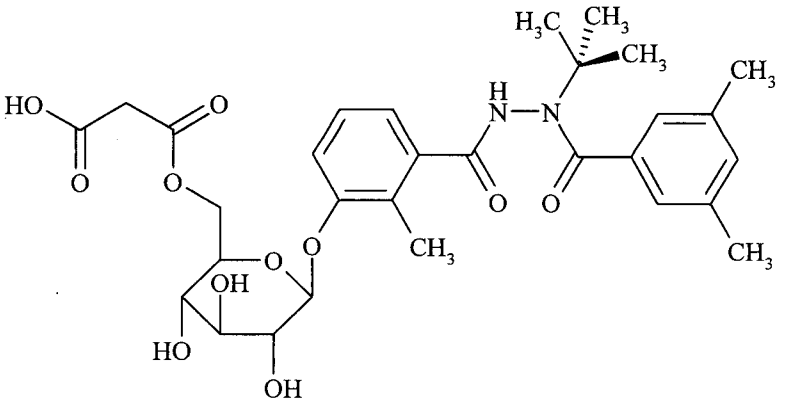
Table A.1. Nomenclature of Methoxyfenozide and its Regulated Metabolites.	
Regulated metabolite	
Company experimental name	RH-7236; RH-117,236; phenol metabolite
Chemical Name	3, 5-dimethylbenzoic acid N-tert-butyl-N'-(3-hydroxy-2-methylbenzoyl)hydrazine
Regulated metabolite	
Company experimental name	RH-1055, RH-151,055, metabolite J-1, glucose conjugate of phenol
Chemical name	3,5-dimethylbenzoic acid N-tert-butyl-N-[3-(β-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide
Regulated metabolite	
Company experimental name	RH-152,072; Metabolite H; Malonyl glucose conjugate of phenol
Chemical name	3,5-dimethylbenzoic acid N-tert-butyl-N'-[3-(β-D-6-malonyl-glucopyranosyl-1-oxy)-2-methylbenzoyl]-hydrazide

Table A.2. Physicochemical Properties of Methoxyfenozide.		
Parameter	Value	Reference
Melting point/range	206.1-208°C	DP# D231303, H. Podall, 5/19/97
pH	7.0	
Density	0.740 ± 0.0081 g.cm^3	
Water solubility (mg/L at 20°C)	3.3	
Solvent solubility (g/L at 20°C)	N-heptane 1.87 Xylene 3.38 1,2-dichloroethane 36.72 Methanol 192.92 2-Propanol 50.22	
Vapor pressure at 25°C	1.33 x 10^{-5} Pa	
Dissociation constant, pK_a	None	
Octanol/water partition coefficient, Log(K_{OW})	3.72 ± 0.04	
UV/visible absorption spectrum	No absorption expected at λ> 300 nm	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

In 12 field rotational crop trials conducted in EPA growing Regions 2, 4, 5, 7, 8, and 11 during 2000, methoxyfenozide (80% WP) was applied to a primary crop of leaf lettuce as five broadcast foliar applications during vegetative development at rates of 0.39-0.41 lb ai/A/application and RTIs of 7-10 days, for a total of 1.99-2.02 lb ai/A (Tables B.1.1 and B.1.2). Applications were made using ground equipment in volumes of 10-32 gal/A, and include the use of a non-ionic surfactant at 0.18-0.25% of the spray volume. The primary lettuce crop was grown to normal maturity and harvested 1-3 days after the last application.

Representative rotational crops of soybeans, wheat, green onions, cucumbers, mustard greens, tomatoes and turnips were planted 6-10 days after the last application (~7-day PBI). The numbers of field sites planted with each crop were as follows: 6 sites each for soybeans and wheat, 4 sites for turnips, 3 sites for mustard greens, 2 sites each for cucumbers and tomatoes, and 1 site for green onions. The growing regions for each crop are presented in Table B.1.3. The rotational crops were grown according to standard agricultural practices, and harvested at the appropriate stage of maturity.

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TABLE B.1.1 Trial Site Conditions.

Trial Identification (City, State; Year)	Soil characteristics			
	Soil Type	%OM	pH	CEC meq/g
Chula, GA 2000	Loamy Sand	0.9	6.0	5.2
Athens, GA 2000	Sandy Clay Loam	1.4	6.3	9.5
Washington, LA 2000	Silt Loam	1.5	5.1	14.4
Greenville, MS 2000	Loam	0.8	6.1	9.1
Brampton, ND 2000	Loam	4.8	7.7	40.5
Sparta, IL 2000	Silt Loam	1.7	6.7	11.8
Dexter, MO 2000	Silt Loam	2.0	7.7	12.3
Arkansaw, WI 2000	Loamy Sand	1.8	6.9	9.6
Delevan, WI 2000	Silt Loam	1.6	5.8	12.2
Velva, ND 2000	Loam	2.2	7.3	33.5
LaSalle, CO 2000	Clay Loam	1.7	8.2	31.9
Payette, ID 2000	Sandy Loam	2.0	7.2	17.9

For all field trial sites, the monthly minimum and maximum air temperatures, the average monthly air temperature, and the total monthly precipitation were reported for the trial period, along with their deviation from the historical average temperature and precipitation. No unusual weather conditions were noted at any test site during the study period. Supplemental irrigation was provided as needed. The field trials were conducted according to normal agricultural practices for the different regions, and information was provided on maintenance pesticides and fertilizers used at each site.

TABLE B.1.2. Study Use Pattern.

Location (City, State; Year) Trial ID	End-use Product	Application Information [1]					Rotational Crops
		Method; Timing	Volume (gal/A)	Single Rate (lb ai/A)	RTI [2] (days)	Total Rate (lb ai/A)	
Chula, GA 2000 11	80% WP	Five broadcast foliar applications to the primary leaf lettuce crop	29-32	0.40	7-10	2.0	Wheat, turnip, mustard greens
Athens, GA 2000 12	80% WP	Five broadcast foliar applications to the primary leaf lettuce crop	29-31	0.40	7-9	2.0	Soybean, cucumber, tomato
Washington, LA 2000 13	80% WP	Five broadcast foliar applications to the primary leaf lettuce crop	13-17	0.40-0.41	7-8	2.01	Wheat, turnip, mustard greens
Greenville, MS 2000 14	80% WP	Five broadcast foliar applications to the primary leaf lettuce crop	10	0.40-0.41	7	2.01	Soybean
Brampton, ND 2000 15	80% WP	Five broadcast foliar applications to the primary leaf lettuce crop	20	0.40	7	2.0	Wheat
Sparta, IL 2000 16	80% WP	Five broadcast foliar applications to the primary leaf lettuce crop	14-16	0.39-0.40	7-8	1.99	Soybean, cucumber
Dexter, MO 2000 17	80% WP	Five broadcast foliar applications to the primary leaf lettuce crop	10-11	0.40	7-10	2.0	Soybean, tomato
Arkansaw, WI 2000 18	80% WP	Five broadcast foliar applications to the primary leaf lettuce crop	20	0.40	7	2.0	Soybean, turnip, green onion

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TABLE B.1.2. Study Use Pattern.

Location (City, State; Year) Trial ID	End-use Product	Application Information [1]					Rotational Crops
		Method; Timing	Volume (gal/A)	Single Rate (lb ai/A)	RTI [2] (days)	Total Rate (lb ai/A)	
Delevan, WI 2000 19	80% WP	Five broadcast foliar applications to the primary leaf lettuce crop	20-21	0.40-0.41	7-8	2.01	Soybean, turnip, mustard greens
Velva, ND 2000 20	80% WP	Five broadcast foliar applications to the primary leaf lettuce crop	15	0.40	7	2.0	Wheat
LaSalle, CO 2000 21	80% WP	Five broadcast foliar applications to the primary leaf lettuce crop	11-12	0.39-0.41	7-10	2.02	Wheat
Payette, ID 2000 22	80% WP	Five broadcast foliar applications to the primary leaf lettuce crop	30-31	0.40-0.41	7	2.01	Wheat

[1] Each application included the use of LATRON CS-7 (non-ionic surfactant) as an adjuvant at 0.18-0.25% v/v.
[2] RTI = Retreatment Interval

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Regions [1]	Representative Rotational Crops						
	Wheat	Soybean	Turnip	Mustard greens	Tomato	Cucumber	Green onion
1	--	--	--	--	--	--	--
2	1	1	1	1	1	1	
3	--	--	--	--	--	--	--
4	1	1	1	1	--	--	--
5	1	4	2	1	1	1	1
6	--	--	--	--	--	--	--
7	1	--	--	--	--	--	--
8	1	--	--	--	--	--	--
9	--	--	--	--	--	--	--
10	--	--	--	--	--	--	--
11	1	--	--	--	--	--	--
12	--	--	--	--	--	--	--
13	--	--	--	--	--	--	--
Total	6	6	4	3	2	2	1

[1] Only regions in the U.S. are reported.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of the appropriate RACs were collected at normal maturity: 89-270 DAP for wheat forage, 138-307 DAP for wheat hay, 161-339 DAP for wheat grain and straw, 38-60 DAP for soybean forage, 58-105 DAP for soybean hay, 103-146 DAP for soybean seed, 47-112 DAP for turnip tops and roots, 41-112 DAP for mustard greens, 51-62 DAP for cucumber, 45-107 DAP for tomato, and 70 DAP for green onions. Samples were placed in labeled sample bags, weighed and stored frozen at the field site for 0-75 days. Samples were shipped frozen via ACDS freezer truck or via Federal Express overnight service with dry

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ice to Rohm and Haas Company. Samples were processed at Rohm and Haas Company and then shipped to SFBC Analytical Laboratories Inc. (Formerly Keystone Laboratories). All samples were received frozen and stored frozen until extraction and analysis.

B.3. Analytical Methodology

Residues of methoxyfenozide and its regulated metabolites were determined in high- and low-moisture rotational crops using an HPLC/UV or MS method (Method TR 34-00-41). This method is the current tolerance enforcement method for rotational crops and was reviewed in the original petition for rotational crop tolerances (DP# 269986, M. Nelson, 07/AUG/2002). The method consists of a combination of two separately named methods, which are used for crop matrices of differing moisture content. Method TR 34-99-74 (HPLC/UV) is intended for the analysis of residues of methoxyfenozide *per se* in high moisture rotational crops. Method TR 34-00-28 (HPLC /MS) is intended for the analysis of residues of methoxyfenozide and its metabolites RH-117,236, and RH-151,055 + RH-152,072 (sugar conjugates, both determined as RH-151,055) in low moisture rotational crops.

For high moisture crops (tomatoes, cucumbers, onions, mustard greens, and turnips), residues were extracted with methanol:0.1N HCl (90:10, v/v), filtered, diluted with 10% NaCl solution, and partitioned against hexane, discarding the hexane fraction. Residues were then partitioned into MDC, concentrated and redissolved in ethyl acetate:hexane (5:95, v/v). Residues of parent were then cleaned up by elution through a basic alumina column and an ENVI-CARB (carbon) SPE cartridge. Residues were quantified by HPLC/UV using external standards, with confirmatory analysis by HPLC/MS using the m/z 367 ion. The validated method LOQ for methoxyfenozide in high moisture commodities is 0.02 ppm and the LOD is 0.006 ppm.

For low moisture crops (wheat and soybean), residues were extracted with methanol:water (90:10, v/v), filtered, diluted with 10% NaCl solution, and partitioned against hexane, discarding the hexane fraction. The remaining methanol:water fraction was diluted further with water and 10% NaCl and then partitioned with MDC:hexane (80:20, v/v). Residues of parent and RH-117,236, which partitioned into the MDC:hexane fraction, were then concentrated and cleaned up by elution through a Florisil column and an ENVI-CARB SPE cartridge. Residues of parent and RH-117,236 were quantified by HPLC/MS using external standards and monitoring the m/z 367 and 353 ions for parent and RH-117236, respectively. The sugar conjugates (RH-152,072 and RH-151,055), which remained in the methanol:water fraction, were then heated for 3 hours at ~100°C to remove the methanol and convert RH-152,072 into RH-151,055. The resulting residues of RH-151,055 were then purified by elution through C-18 and ENI-CARB SPE cartridges. Residues of RH-151,055 were then quantified by HPLC/MS using external standards and monitoring the m/z 515 ion. The validated method LOQ for methoxyfenozide and RH-117,236 in low-moisture crops is 0.02 ppm, and the LOD is 0.006 ppm. The validated method LOQ for RH-151,055 in low-moisture crops is 0.05 ppm, and the LOD is 0.015 ppm. For calculating combined residues, residues of RH-117,236 and RH-151,055 were converted to parent equivalents by multiplying by the molecular weight conversion factors of 1.04 and 0.715, respectively.

The above methods were validated in conjunction with the analysis of field trial samples, using control samples fortified with methoxyfenozide, RH-117,236 and RH-151,055 at 0.02-1.0 ppm.

C. RESULTS AND DISCUSSION

The HPLC/UV or MS methods (TR 34-00-41) used to determine residues of methoxyfenozide and its metabolites in rotational crops were adequately validated in conjunction with the analysis of field trial samples. Average recoveries from low moisture crops were 88-94% with standard deviations of 6-17% for methoxyfenozide, 87-97% with standard deviations of 5-19% for RH-117,236, and 86-109% with standard deviations of 5-18% for RH-151,055 (Table C.1). The average recovery of methoxyfenozide from high moisture crops was 80-96% with standard deviations of 8-25%. Apparent residues were <LOQ in/on all but three control samples, where the first analysis of the sample returned residue values of 0.040-0.050 ppm, and a second analysis returned a value <LOQ. Adequate sample calculations and example chromatograms were provided, and the concurrent fortifications bracketed residues in treated samples.

Samples from the high-moisture crops were stored frozen for 4.6-17.1 months prior to extraction for analysis of methoxyfenozide, and samples from low-moisture crops were stored frozen for 6.5-13.6 months prior to extraction for analysis of parent the its regulated metabolites (Table C.2). Adequate storage stability data are available indicating methoxyfenozide is stable under frozen conditions for up 12 months in apples, head lettuce, and tomatoes, and 23.5 months in cottonseed. Data are also available from the confined rotational crop study indicating that residues of methoxyfenozide and its metabolites were stable in frozen wheat forage for up to 4 years. These data will support the storage intervals and conditions incurred by the field rotational crop samples.

Methoxyfenozide residues were <LOQ (<0.02 ppm) for all samples of rotational wheat forage, wheat grain, soybean seed, turnip roots, tomatoes and cucumbers (Table 3). Residues of parent were <0.02-0.022 ppm for wheat hay, <0.02-0.023 ppm for wheat straw, <0.02-0.077 for soybean forage, <0.02-0.136 ppm for soybean hay, <0.03-0.038 ppm for turnip tops, <0.02-0.031 ppm for mustard greens and 0.028-0.060 ppm for green onions. Average residues of parent were 0.02 ppm for wheat forage, hay, straw and grain, as well as soybean seed, turnip roots, cucumber and tomato (Table C.4). Parent residues averaged 0.044 ppm for soybean forage and green onions, 0.064 ppm for soybean hay, and 0.022 ppm for turnip tops and mustard greens.

Residues of the phenol metabolite (RH-117,236) were <LOQ (<0.02 ppm) for all samples of wheat grain and soybean seed. Residues of RH-117,236 were 0.017-0.038 ppm for wheat forage, <0.02-0.510 ppm for wheat hay, 0.153-0.841 ppm for wheat straw, <0.02-0.058 ppm for soybean forage, and <0.02-0.218 ppm for soybean hay. Average RH-117,236 resides were 0.02 ppm for wheat grain and soybean seeds, 0.023 ppm for wheat forage, 0.125 ppm for wheat hay, 0.345 ppm for wheat straw, 0.026 ppm for soybean forage, and 0.75 ppm for soybean hay.

Residues of RH-151,055 (including RH-152,072) were <LOQ (<0.05 ppm) in wheat grain, 0.091-1.318 ppm for wheat forage, 0.218-0.857 ppm for wheat hay, 0.123-0.845 ppm for wheat straw, <0.05-0.376 ppm for soybean forage, <0.050-0.907 ppm for soybean hay, and <0.050-

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0.768 ppm for soybean seed (Table C.3). Average residues of RH-151,055 were 0.612 ppm for wheat forage, 0.544 ppm for wheat hay, 0.05 ppm for wheat grain, 0.462 ppm for wheat straw, 0.190 ppm for soybean forage, 0.455 for soybean hay and 0.142 ppm for soybean seed.

In the low-moisture crops (wheat and soybean), combined residues of methoxyfenozide, RH-117,236 and RH-151,055/RH-152,072 (expressed in parent equivalents) were 0.106-1.002 ppm in wheat forage, 0.274-0.912 ppm in wheat hay, <LOQ (<0.077 ppm) in wheat grain, 0.329-1.278 ppm in wheat straw, <0.077-0.359 ppm in soybean forage, <0.077-0.738 ppm in soybean hay, and <0.077-0.590 ppm in soybean seed. Average combined residues were 0.481 ppm in wheat forage, 0.539 ppm in wheat hay, <0.077 ppm in wheat grain, 0.710 ppm in wheat straw, 0.207 ppm in soybean forage, 0.468 ppm for soybean hay, and 0.143 ppm for soybean seed.

Common cultural practices were used to maintain plants, and the weather conditions and maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Concurrent Recoveries of Methoxyfenozide and Its Metabolites from Rotational Crop Matrices.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)			Mean ± std dev (%)		
			Methoxyfenozide	RH-117,236	RH-151,055	Methoxyfenozide	RH-117,236	RH-151,055
Soybean Seed	0.05	7	51[1], 117, 100, 96, 109, 73, 98	83, 76, 103, 72, 102, 140, 76	40[1], 92, 82, 90, 85, 81, 84	94±17	92± 19	86± 10
	0.5	7	106, 72, 105, 102, 108, 73, 68	90, 62, 101, 98, 87, 93, 99	50[1], 87, 79, 111, 95, 68, 81			
Wheat Forage	0.1	3	101, 92, 91	100, 92, 82	104, 94, 97	91± 6	93 ± 7	96± 5
	1.0	3	91, 85, 85	99, 94, 88	88, 95, 96			
Wheat Hay	0.1	3	103, 96, 94	99, 107, 82	103, 106, 111	95± 6	97 ± 9	109± 11
	1.0	3-4	98, 85, 91	96, 97, 106, 91	90, 117, 125, 109			
Wheat Grain	0.1	3	101, 82, 89	97, 65, 89	88, 111, 98	88± 9	87± 12	93± 10
	1.0	3	95, 76, 87	97, 84, 87	85, 88, 89			
Wheat Straw	0.1	3	105, 98, 90	15[1], 84, 89	91, 112, 107	91± 14	90± 5	95± 18
	1.0	3	94, 65, 93	90, 97, 89	111, 84, 67			
Mustard Greens	0.02	5	101, 83, 85, 120, 118	--	--	96± 15	--	--
	0.1	4	94, 89, 75, 100	--	--			
Tomato	0.02	1	74	--	--	80± 8	--	--
	0.1	1	85	--	--			
Turnip Root	0.02	4	122, 49, 103, 102	--	--	89 ± 25	--	--
	0.1	4	109, 69, 70, 90	--	--			

[1] Values not used to calculated averages.

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration (Months) [1]	Interval of Demonstrated Storage Stability (Months) [2]
Soybean Forage	-20	10.7-14.3	48
Soybean Hay		9.8-13.6	48
Soybean Seed		6.5-12.1	48
Wheat Forage		10.1-12.6	48
Wheat Hay		8.8-11.0	48
Wheat Grain		7.7-10.3	48
Wheat Straw		7.8-10.5	48
Green Onion		8.2	12
Cucumber		8.6-9.1	12
Mustard Greens		4.8-17.1	12
Tomato		9.6-10.7	12
Turnip Tops		4.6-16.8	12
Turnip Root		4.6-16.8	12

[1] Interval from harvest to analysis. The storage duration for extracts was not reported.
[2] DP# 269986, M. Nelson, 07/AUG/2002.

TABLE C.3. Methoxyfenozide Metabolite Residues in Rotational Crops.

Trial ID (City, State; Year)	EPA growing Regions	Crop; Variety	Commodity	Total Rate (lb ai/A)	Harvest (DAP) [1]	PBI [2] (days)	Residues (ppm) [3]					
							Methoxyfenozide		RH-117,236		RH-151,055 [4]	
Chula, GA 2000 11	2	Wheat; Pioneer 2684	Forage	2.0	92	8	(0.007)	(0.006)	0.020	(0.017)	0.973	0.703
			Hay		154		(0.011)	0.022	0.449	0.510	0.382	0.503
			Grain		181		ND[5]	ND	ND	ND	ND	ND
			Straw		181		0.023	(0.015)	0.841[6]	0.674[6]	0.532	0.617
		Turnip; Purple Top White Globe	Roots		112	8	(0.013)	(0.006)	--	--	--	--
			Tops		112		(0.012)	(0.011)	--	--	--	--
		Mustard Greens; Florida Broadleaf	Greens		112	8	(0.017)	0.031	--	--	--	--
Athens, GA 2000 12	2	Soybean; S73-Z5	Forage	2.0	53	7	0.056	0.069	ND	ND	0.372	0.376
			Hay		105		0.051	0.099	0.215	0.218	0.479	0.504
			Seed		146		ND	ND	ND	ND	ND	ND
		Cucumber; Long green imperial	Fruit		62	7	(0.008)	(0.007)	--	--	--	--
		Tomato; Better Boy	Fruit		107	7	ND	ND	--	--	--	--
Washington, LA 2000 13	4	Wheat; Mason	Forage	2.01	89	8	ND	ND	ND	ND	0.091	0.104
			Hay		138		ND	ND	0.086	0.094	0.262	0.218
			Grain		161		ND	ND	ND	ND	ND	ND
			Straw		161		ND	ND	0.277	0.420	0.242	0.188
		Turnip; Purple Top White Globe	Roots		100	7	ND	ND	--	--	--	--
			Tops		100		ND	ND	--	--	--	--
		Mustard greens; India	Greens		91	7	ND	ND	--	--	--	--
Greenville, MS 2000 14	4	Soybean; DP 5960 RR	Forage	2.01	50	7	0.054	0.044	ND	ND	0.146	0.233
			Hay		67		0.037	0.069	ND	ND	0.785[7]	0.907[7]
			Seed		140		ND	ND	ND	ND	0.768[8]	0.439
Brampton, ND 2000 15	5	Wheat; Harding	Forage	2.0	239	7	ND	(0.010)	(0.012)	0.034	0.494	0.495
			Hay		277		ND	ND	0.090	0.063	0.622	0.433
			Grain		317		ND	ND	ND	ND	ND	ND
			Straw		317		(0.013)	(0.011)	0.246	0.350	0.163	0.123

TABLE C.3. Methoxyfenozide Metabolite Residues in Rotational Crops.

Trial ID (City, State; Year)	EPA growing Regions	Crop; Variety	Commodity	Total Rate (lb ai/A)	Harvest (DAP) [1]	PBI [2] (days)	Residues (ppm) [3]					
							Methoxyfenozide		RH-117,236		RH-151,055 [4]	
Sparta, IL 2000 16	5	Soybean; Hisoy	Forage	1.99	44	10	0.055	0.077	ND	ND	0.185	0.330
			Hay		69		0.042	0.122	ND	ND	0.613	0.798
			Seed		111		ND	ND	ND	ND	ND	ND
		Cucumber; Market More 76	Fruit		51	10	(0.007)	(0.011)	--	--	--	--
Dexter, MO 2000 17	5	Soybean; Pioneer 9492	Forage	2.0	60	6	ND	ND	ND	ND	ND	ND
			Hay		82		ND	ND	ND	ND	ND	ND
			Seed		131		ND	ND	ND	ND	ND	ND
		Tomato; Better Bush	Fruit		45	7	(0.009)	ND	--	--	--	--
Arkansaw, WI 2000 18	5	Soybean; Asgrow AU868	Forage	2.0	38	7	(0.007)	ND	0.058	0.056	0.183	0.133
			Hay		58		(0.018)	0.019	0.152	0.158	0.378	0.367
			Seed		103		ND	ND	ND	ND	ND	ND
		Green onions; White Libson	onions		70	7	0.060[9]	0.028[9]	--	--	--	--
		Turnip; Purple Top White Globe	Roots		61	7	ND	(0.006)	--	--	--	--
			Tops		61		(0.011[10])	(0.009[10])	--	--	--	--
Delevan, WI 2000 19	5	Soybean; Brand #198	Forage	2.01	47	7	0.056	0.037	ND	0.006	0.108	0.110
			Hay		59		0.134	0.136	(0.012)	(0.013)	0.262	0.268
			Seed		110		ND	ND	ND	ND	ND	ND
		Mustard Greens; India	Greens		41	7	(0.012)	(0.011)	--	--	--	--
		Turnip; Purple Top White Globe	Roots		47	7	(0.006)	ND	--	--	--	--
			Tops		47		0.038	<0.006	--	--	--	--
Velva, ND 2000 20	7	Wheat; Elkhorn	Forage	2.0	270	7	(0.016)	(0.015)	0.038	0.026	1.318	0.943
			Hay		307		(0.011)	(0.010)	(0.015)	(0.008)	0.857	0.675
			Grain		339		ND	ND	ND	ND	ND	ND
			Straw		339		ND	ND	0.163	0.208	0.313	0.369
LaSalle, CO 2000 21	8	Wheat; Platte	Forage	2.02	212	7	ND	ND	(0.013)	0.020	0.805	0.639
			Hay		270		ND	(0.011)	0.061	0.054	0.529	0.559
			Grain		290		ND	ND	ND	ND	ND	ND
			Straw		290		(0.014)	(0.017)	0.153	0.403	0.845	0.731
Payette, ID 2000 22	11	Wheat; Stephens	Forage	2.01	176	7	ND	(0.008)	(0.008)	(0.009)	0.464	0.313
			Hay		245		ND	ND	0.027	0.024	0.650	0.837
			Grain		294		ND	ND	ND	ND	ND	ND
			Straw		294		ND	ND	0.164	0.243	0.698	0.725

1 DAP = Days after planting.
2 PBI = Plant-back Interval.
3 The individual residues are expressed in terms of the individual analytes. The LOQ in each matrix is 0.02 ppm for methoxyfenozide and RH-117,236 and 0.05 ppm for RH-151,055; and the LODs are 0.006 ppm for methoxyfenozide and RH-117,236 and 0.015 ppm for RH-151,055. Residues <LOQ but ≥LOD are reported in parenthesis
4 Includes residues of RH-152,072.
5 ND = Not Detected
6 Control Value was 0.040 ppm, but was ND after reanalysis.
7 Control Value was 0.041 ppm, but was ND after reanalysis
8 Mean of duplicate analyses.
9 Control value was 0.017 ppm.
10 Control Value was 0.050 ppm, and reanalyzed at 0.088 ppm.

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TABLE C.4. Summary of Residue Data from Limited Rotational Crop Field Trials with Methoxyfenozide.

Rotational Crop Commodity	Applic. Rate (lb ai/A)	PBI (days)	Residue Levels (ppm) [1]						
			n	Min.	Max.	HAFT [2]	Median	Mean	Std. Dev.
Methoxyfenozide									
Wheat Forage	1.99-2.02	6-10	12	<0.020	<0.020	<0.020	0.020	0.020	NA[3]
Wheat Hay			12	<0.020	0.022	0.021	0.020	0.020	0.001
Wheat Grain			12	<0.020	<0.020	<0.020	0.020	0.020	NA
Wheat Straw			12	<0.020	0.023	0.022	0.020	0.020	0.001
Soybean Forage			12	<0.020	0.077	0.066	0.049	0.044	0.020
Soybean Hay			12	<0.020	0.136	0.135	0.047	0.064	0.047
Soybean Seed			12	<0.020	<0.020	<0.020	0.020	0.020	NA
Turnip Roots			8	<0.020	<0.020	<0.020	0.020	0.020	NA
Turnip Tops			8	<0.020	0.038	0.029	0.020	0.022	0.006
Mustard Greens			6	<0.020	0.031	0.026	0.020	0.022	0.004
Cucumber Fruit			4	<0.020	<0.020	<0.020	0.020	0.020	NA
Tomato Fruit			4	<0.020	<0.020	<0.020	0.020	0.020	NA
Green Onions			2	0.028	0.060	0.044	0.044	0.044	0.023
RH-117,236									
Wheat Forage	1.99-2.02	6-10	12	0.017	0.038	0.032	0.020	0.023	0.006
Wheat Hay			12	<0.020	0.510	0.480	0.062	0.125	0.168
Wheat Grain			12	<0.020	<0.020	0.020	0.020	0.020	NA
Wheat Straw			12	0.153	0.841	0.758	0.262	0.345	0.215
Soybean Forage			12	<0.020	0.058	0.057	0.020	0.026	0.014
Soybean Hay			12	<0.020	0.218	0.217	0.020	0.075	0.084
Soybean Seed			12	<0.020	<0.020	<0.020	0.020	0.020	NA
RH-151,055+RH-152,072									
Wheat Forage	1.99-2.02	6-10	12	0.091	1.318	1.131	0.567	0.612	0.363
Wheat Hay			12	0.218	0.857	0.766	0.544	0.544	0.201
Wheat Grain			12	<0.050	<0.050	<0.050	0.050	0.050	NA
Wheat Straw			12	0.123	0.845	0.788	0.451	0.462	0.258
Soybean Forage			12	<0.050	0.376	0.374	0.165	0.190	0.116
Soybean Hay			12	<0.050	0.907	0.846	0.429	0.455	0.282
Soybean Seed			12	<0.050	0.768	0.604	0.050	0.142	0.227
Combined Residues [4]									
Wheat Forage	1.99-2.02	6-10	12	0.106	1.002	0.862	0.453	0.481	0.263
Wheat Hay			12	0.274	0.912	0.836	0.518	0.539	0.184
Wheat Grain			12	<0.077	<0.077	<0.077	0.077	0.077	NA
Wheat Straw			12	0.392	1.278	1.220	0.640	0.710	0.295
Soybean Forage			12	<0.077	0.359	0.351	0.194	0.207	0.096
Soybean Hay			12	<0.077	0.738	0.679	0.475	0.468	0.227
Soybean Seed			12	<0.077	0.590	0.472	0.077	0.143	0.162

[1] The individual residues are expressed in terms of the individual analytes. The LOQ is 0.02 ppm for methoxyfenozide and RH-117,236 in each matrix and 0.05 ppm for RH-151,055, for a combined LOQ of 0.09 ppm. The LOQ was used for residue values of <LOQ in all calculations.

[2] HAFT = Highest Average Field Trial.

[3] NA = Not Applicable

[4] Combined residues are expressed in parent equivalents. For combining residues, residues of RH-117,236 and RH-151,055 were converted to parent equivalents by multiplying by 1.04 and 0.715, respectively.

D. CONCLUSION

The field accumulation in rotational crop study is adequate. Geographic representation of the rotational crop was adequate. The analytical methods used are adequate and were validated in conjunction with the analysis of field trial samples. The available data will support a PBI of 7

days for rotational crops planted following application of methoxyfenozide at rates totaling 2 lb ai/A/season.

E. REFERENCES

DP#: 269986 and 274542
Subject: Methoxyfenozide in/on Various Rotational Crops. Residue Chemistry Review.
From: M. Nelson
To: M. Laws/J. Tavano
Dated: 07/AUG/2002
MRIDs: 45194701, 45194702, 45194703, 45194704

F. DOCUMENT TRACKING

RDI: DNR (07/APR/2009); WC (27/ARP/2009)
Petition Numbers: 0F06201
DP#: 322948
PC Code: 121207

Template Version June 2005

Methoxyfenozide/121027/Dow AgroSciences
DACO 7.2.4/OPPTS 860.1360/OECD IIIA 5.3.1
Multiresidue Analytical Methods

Primary Evaluator	Debra Rate, Ph.D., Biologist Alterntive Risk Integration and Assessment (ARIA) Risk Integration, Minor Use, and Emergency Response Branch (RIMUERB) / Registration Division (RD; 7505P)	Date: 07/APR/2009
Approved by	William Cutchin, Acting Senior Branch Scientist ARIA/RIMUERB/RD (7505P)	

This DER was originally prepared under contract by Dynamac Corporation (submitted 31/JAN/2008). The DER has been reviewed by ARIA and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

MRID No. 46039301 Conrath, B.; Anderson, C. (2001) Multriesidue Method Testing for RH-117,236, RH-141,518, RH-151,055, and RH-152,072 According to PAM I, Appendix II, as Updated January 1994. Project Number: 46294, 34/01/33. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 217 p.

EXECUTIVE SUMMARY:

Dow AgroSciences submitted multiresidue method testing data on four regulated metabolites of methoxyfenozide: the glucuronide animal metabolite RH-141,518; the free phenol metabolite RH-117,236; and the glucose and malonylglycosyl conjugates of RH-117,236 (RH-151,055 and RH-152,072).

Testing under Protocol A indicated that all four metabolites are fluorescent; however, only two metabolites (RH-117,236 and RH-151,055) chromatographed acceptably under the specified high performance liquid chromatography (HPLC) conditions, and these metabolites were not recovered from the required Celite/charcoal cleanup procedures. Therefore, testing through Protocol A was discontinued.

Metabolite RH-117,236 was tested through Protocol B as it has a phenol moiety. Its was shown to chromatograph acceptably using Level II conditions (230°C) with Module DG-10. However, the specified methylation procedures did not yield appreciable quantities of its methyl ether (RH-112,485, parent). Under Protocol C, Metabolites RH-141,518, RH-151,055 and RH-152,072 did not chromatograph acceptably on any of the column-detector combinations under Level I conditions; however, all four metabolites were shown to chromatograph acceptably under Level II conditions using Module DG-10. As electron capture detection was used for analysis, the recovery of each analyte was also evaluated from the Florisil column cleanup procedures under Protocols D and E. As none of the metabolites were recovered (<30%) from the required Florisil column cleanup, no further testing was conducted through Protocols D and E. Testing through Protocol G was not conducted as none of these metabolites are substituted urea compounds.

Based on the testing data, the FDA Multiresidue Methods are not suitable for analysis of these metabolites.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the multiresidue method testing data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 322948.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study was conducted in compliance with the U.S. EPA GLP Standards, 40 CFR 160, except that the characterization of the retention time marker and relative response standards, as well as the Florisil calibration standards, were conducted by their respective commercial suppliers and the GLP status of these characterizations is unknown. None of these reported deviations had an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Methoxyfenozide is a diacylhydrazine insecticide used on a variety of crops for control of armyworms and other lepidopterous pest species. Methoxyfenozide mimics the action of the molting hormone of lepidopterous larvae, causing the larvae to undergo an incomplete and premature molt, which ultimately results in their death. Methoxyfenozide is currently registered to Dow AgroSciences. Permanent tolerances are established for methoxyfenozide *per se* on a wide variety of plant commodities at levels ranging from 0.05 ppm in/on field corn grain and sweet corn ears to 160 ppm in/on soybean aspirated grain fractions [40 CFR §180.544(a)(1)].

As a condition of establishing tolerances on rotational crops (DP# 269986, M. Nelson, 07/AUG/2002) and poultry commodities (DP# 269969, M. Nelson, 07/AUG/2002), the Agency required data on the recovery of four methoxyfenozide metabolites through FDA multiresidue method protocols. The four metabolites are the glucuronide conjugate RH-141,518, which is a regulated metabolite in poultry commodities, and RH-117,236, RH-151,055, and RH-152,072, which are regulated residues in low-moisture rotational crops. The current submission contains information on the recovery of these four metabolites through the multiresidue testing protocols. The nomenclature of methoxyfenozide and its regulated metabolites is presented in Table A.1, and the physicochemical properties of methoxyfenozide are listed in Table A.2.

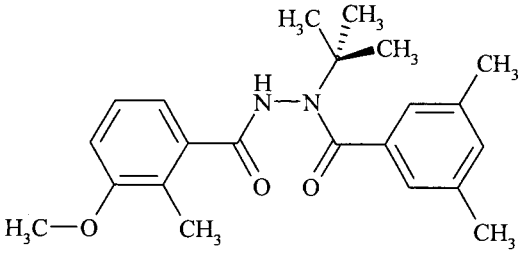
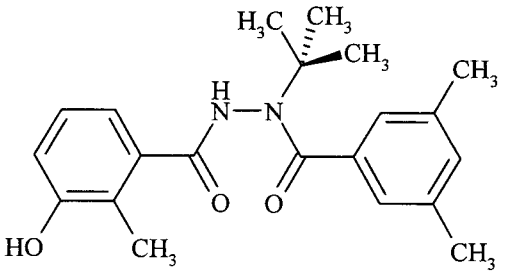
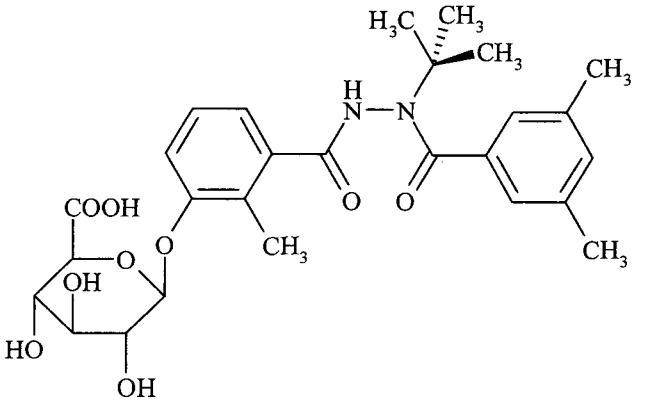
Table A.1. Nomenclature of Methoxyfenozide and its Regulated Metabolites.	
Chemical structure	
Common name	Methoxyfenozide
Company experimental name	RH-2485
IUPAC name	N-*tert*-butyl-N′-(3-methoxy-*o*-toluoyl)-3,5-xylohydrazide
CAS name	3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide
CAS registry number	161050-58-4
Chemical structure	
Common name	Free phenol metabolite of methoxyfenozide
Company experimental name	RH-117,236
CAS name	3,5-dimethylbenzoic acid N -tert-butyl- N ′-(3-hydroxy-2-methylbenzoyl) hydrazide
Chemical structure	
Common name	Glucuronide conjugate of methoxyfenozide
Company experimental name	RH-141,518; Metabolite G
CAS name	β-D-Glucopyranuronic acid, 3-[2-(1,1-dimethylethyl)-2-(3,5-dimethylbenzoyl)-hydrazino]carbonyl-2-methylphenyl-]

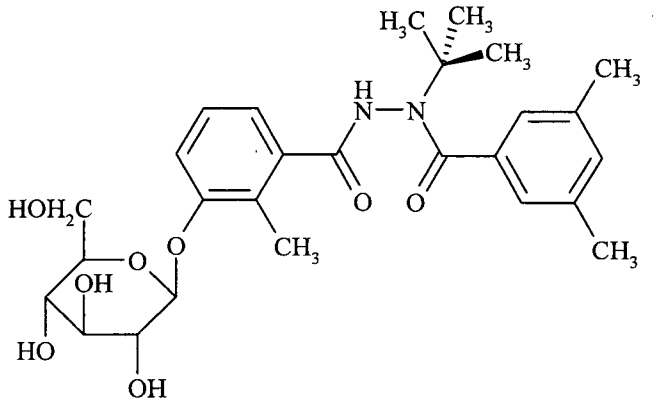
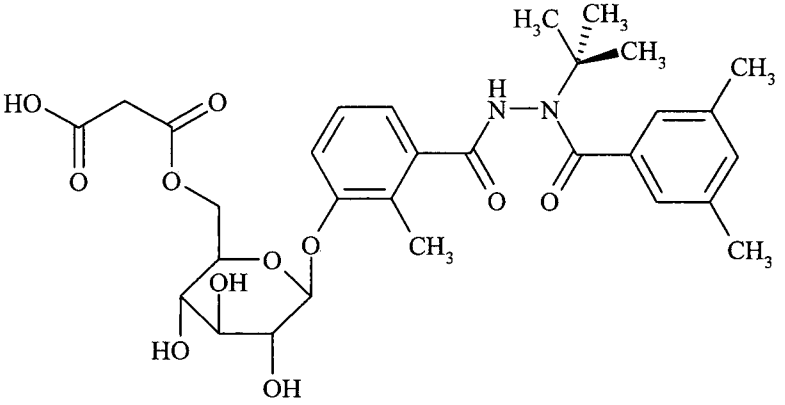
Table A.1. Nomenclature of Methoxyfenozide and its Regulated Metabolites.	
Chemical structure	
Common name	Glucose conjugate of phenol metabolite
Company experimental name	RH-151,055; Metabolite J
CAS name	3,5-dimethylbenzoic acid N-tert-butyl-N-[3-(β-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide
Chemical structure	
Common name	Malonyl glucose conjugate of phenol metabolite
Company experimental name	RH-152,072; Metabolite H
CAS name	3,5-dimethylbenzoic acid N-tert-butyl-N′-[3-(β-D-6-malonyl-glucopyranosyl-1-oxy)-2-methylbenzoyl]-hydrazide

Table A.2. Physicochemical Properties of Methoxyfenozide.		
Parameter	Value	Reference
Melting point/range	206.1-208°C	DP# 231303, H. Podall, 19/MAY/1997
pH	7.0	
Density	0.740 ± 0.0081 g.cm^3	
Water solubility (mg/L at 20°C)	3.3	
Solvent solubility (g/L at 20°C)	N-heptane 1.87 Xylene 3.38 1,2-dichloroethane 36.72 Methanol 192.92 2-Propanol 50.22	
Vapor pressure at 25°C	1.33 x 10^{-5} Pa	
Dissociation constant, pK_a	None	
Octanol/water partition coefficient, $Log(K_{OW})$	3.72 ± 0.04	
UV/visible absorption spectrum	No absorption expected at λ> 300 nm	

B. MATERIALS AND METHODS

All four compounds were tested using Protocol A and were found to be naturally fluorescent at an excitation wavelength of 280 nm. However, subsequent HPLC analysis indicated that only RH-117,236 and RH-151,055 yielded peaks with acceptable retention times and adequate sensitivity. No peak was detected for RH-152,072 and only a weak peak was detected for RH-141,518; therefore no further testing was conducted on these two metabolites. Testing for RH-117,236 and RH-151,055 through the Celite/charcoal cleanup column indicated that these compounds could not be recovered from the column; therefore, testing through Protocol A was terminated.

As RH-117,236 is a phenol it was tested through Protocol B. Both RH-117,236 and its methyl ether (RH-112,485; methoxyfenozide) gave an adequate response when tested under Level II conditions of 230°C (DG-10). To determine the methylation efficiency of RH-117,236, the phenol metabolite was dissolved in acetone and heated with 1 M tetrabutylammonium hydroxide and methyl iodide at 40°C for 1.5 hours. The methylated RH-117236 was then compared with the standard using module DG-10.

For Protocol C, Level I testing of RH-141,518, RH-151,055 and RH-152,072 was conducted using three different column types with electron capture detection (Modules DG-1, DG-13 and DG-18). For all three compounds at least one major peak was observed, but the peaks for all four compounds were generally outside the acceptable relative retention time of 0.3-5.0. Therefore they were tested under Level II conditions of 230°C. All three compounds and RH-117,236 yielded acceptable chromatography using module DG-10.

As the test compounds did not chromatograph acceptably using the Level I conditions, they could not be tested using nitrogen-phosphorus detection. Therefore, the optional Florisil column cleanup was necessary. Each of the compounds was tested for recovery from Florisil columns.

For Protocol D, each compound was tested in duplicate for its recovery from the Florisil cleanup procedures described in 302, C1. After loading each compound onto the column, residues were eluted with methylene chloride:acetonitrile:hexane (50:1.5:48.5, v/v/v). The eluates were concentrated and analyzed using module DG-10. As the compounds were not recovered from the Florisil column, testing through Protocol D was terminated.

For Protocol E, each compound was tested in duplicate for its recovery from the Florisil cleanup procedures described in 303, C1 and C2. After loading each compound onto the column, residues were eluted with varying volumes of ethyl ether in petroleum ether (6, 15, and 50% v/v), or sequentially with methylene chloride:hexane (20:80, v/v/v), methylene chloride: acetonitrile:hexane (50:0.35:49.65, v/v/v), and methylene chloride:acetonitrile:hexane (50:1.5:48.5, v/v/v). The eluates were concentrated and analyzed using module DG-10. As the compounds were not recovered from the Florisil column, testing through Protocol E was terminated.

As none of the compounds are substituted urea compounds, testing under Protocol G was not required.

C. RESULTS AND DISCUSSION

The testing of the four metabolites of methoxyfenozide through the FDA Multiresidue Method Testing Protocols is summarized in Table C.1. Although all four metabolites were found to be naturally fluorescent, only two of the metabolites produced HPLC peaks adequate to warrant further testing. Subsequent testing through the Celite/charcoal cleanup procedures indicated that these compounds could not be recovered from the column.

Under Protocol B, the phenol metabolite (RH-117,236) and its methyl ether (RH-112,485, parent) were both shown to chromatograph acceptably under Level II conditions (module DG-10); however, the methylation procedures (402 C1b) did not produce appreciable amounts of the methyl ether. Therefore, further testing through Protocol B was discontinued.

Under Protocol C, Metabolites RH-141,518, RH-151,055 and RH-152,072 did not chromatograph acceptably on any of the column-detector combinations under Level I conditions (Table C.2); however, all four metabolites were shown to chromatograph acceptably under Level II conditions using Module DG-10. As electron capture detection was used for analysis, the recovery of each analyte was evaluated from the Florisil column cleanup procedures under Protocols D and E. None of the metabolites were recovered (<30%) from the Florisil column cleanups. Therefore, no further testing was conducted through Protocols D and E.

TABLE C.1.	**Results of Multiresidue Methods Testing with Metabolites RH-117236, RH-141518, RH-151055, and RH-152072.**	
PAM I Protocol	Results	Comments
A	RH-117,236 - Naturally Fluorescent. Produced an acceptable HPLC peak, but was not recovered (0%) from the Celite/charcoal cleanup column RH-141,518 - Naturally Fluorescent. Produced an HPLC peak which was not sufficient to continue analysis. RH-151,055 - Naturally Fluorescent. Produced an acceptable HPLC peak, but was not recovered from the Celite/charcoal cleanup column RH-152,072 - Naturally Fluorescent. Did not produce an HPLC peak.	No further testing was conducted for Protocol A
B	RH-117,236 - Chromatographs acceptably, but does not produce RH-112,485 (the methyl ether, parent) RH-141,518, RH-151,055, and RH-152,072 were not analyzed as they are not phenols	No further testing was conducted for Protocol B
C	RH-117,236 - Level II testing using module DG-10 gave an adequate response; the RRT was >0.3 and <5.0 compared to phosalone RH-141,518 - Level I testing using module DG-18 and Level II testing using module DG-10 give adequate responses, and retention times were >0.3 and <5.0 compared to phosalone or chlorpyrifos RH-151,055 - Level II testing using module DG-10 gave an adequate response; the RRT was >0.3 and <5.0 compared to phosalone RH-152,072 - Level II testing using module DG-10 gave an adequate response; the RRT was >0.3 and <5.0 compared to phosalone	
D	RH-117,236 - Does not elute off the Florisil column RH-141,518 - Does not elute off the Florisil column RH-151,055 - Does not elute off the Florisil column RH-152,072 - Does not elute off the Florisil column	No further testing under protocol D was conducted
E	RH-117,236 - Does not elute off the Florisil column RH-141,518 - Does not elute off the Florisil column RH-151,055 - Does not elute off the Florisil column RH-152,072 - Does not elute off the Florisil column	No further testing under protocol E was conducted
F	Not tested	No testing under protocol F was conducted.
G	Not tested	Not tested as substances are not substituted urea compounds

Table C.2	Gas Chromatographic Responses for Methoxyfenozide Metabolites.				
Analyte	Module	Column/detector	Retetion time (min)	RRT	ng for 50% FSD
RH-117,236	DG-10	DB-1/EC	13.96	1.72 [1]	67
RH-141,518	DG-1	DB-1/EC	not reported (NR)	10.3 and 12.5 [2]	429 and 729, respectively
	DG-10	DB-1/EC	13.50	1.74 [1]	244
	DG-13	DB-17/EC	NR	20.1 [2]	837
	DG-18	DB-225/EC	NR	0.44, 0.78, 0.91 and 1.96 [2]	497, 905, >1000 and >1000, respectively
RH-151,055	DG-1	DB-1/EC	NR	10.5 and 12.6 [2]	526 and 699, respectively
	DG-10	DB-1/EC	13.72	1.77 [1]	182
	DG-13	DB-17/EC	NR	20.0 [2]	>1000
	DG-18	DB-225/EC	NR	0.14 [2]	97
RH-152,072	DG-1	DB-1/EC	NR	10.3 and 12.5 [2]	280 and 444, respectively
	DG-10	DB-1/EC	13.67	1.77 [1]	151
	DG-13	DB-17/EC	NR	20.1 [2]	>1000
	DG 18	DB-225/EC	NR	1.20 [2]	>1000

[1] Relative to phosalone.
[2] Relative to chlorpyrifos.

D. CONCLUSION

The available multiresidue method testing data are acceptable and indicate that FDA multiresidue methods are not suitable for analysis of methoxyfenozide metabolites. The submitted data will be forwarded to the US FDA for further evaluation.

E. REFERENCES

DP#: 269986 and 274542
Subject: Methoxyfenozide in/on Various Rotational Crops. Residue Chemistry Review.
From: M. Nelson
To: M. Laws/J. Tavano
Dated: 07/AUG/2002
MRIDs: 45194701, 45194702, 45194703, 45194704

DP#: 269969
Subject: PP#0F06213: Methoxyfenozide in/on Field Corn and Sweet Corn; Poultry Tolerances; and, Higher Tolerances on Other Selected Animal Commodities. Residue Chemistry Review.
From: M. Nelson
To: M. Laws/J. Tavano
Dated: 07/AUG/2002
MRIDs: 45213500, 45213502 thru 45213514

F. DOCUMENT TRACKING

RDI: DNR (07/APR/2009); WC (27/APR/2009)
Petition Numbers: 0F06201 and 0F06213
DP#: 322948
PC Code: 121027

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Methoxyfenozide/121027/Dow AgroSciences
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial – Plum

Primary Evaluator Debra Rate, Ph.D., Biologist Date: 07/APR/2009
Alterntive Risk Integration and Assessment (ARIA)
Risk Integration, Minor Use, and Emergency Response
Branch (RIMUERB) / Registration Division (RD; 7505P)

Approved by William Cutchin, Acting Senior Branch Scientist
ARIA/RIMUERB/RD (7505P)

This DER was originally prepared under contract by Dynamac Corporation (submitted 31/JAN/2008). The DER has been reviewed by ARIA and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

MRID No. 46606301 Dolder, S.; Lindsay, D. (2005) Magnitude of the Residue of Methoxyfenozide in Plums. Project Number: 40018, 040018PL1, 040018PL2. Unpublished study prepared by Dow AgroSciences LLC, Dowelanco and Qualls Agricultural Laboratories. 29 p.

EXECUTIVE SUMMARY:

Dow AgroSciences, LLC, has submitted supplemental field trial data for methoxyfenozide on plums from two field trials conducted in EPA growing Regions 10 and 11 during 2004. In each field trial, a 2 lb/gal flowable concentrate (FlC) formulation of methoxyfenozide was applied to plum trees as four broadcast foliar applications during fruit development and maturation, at rates of 0.25-0.27 lb ai/A/application and retreatment intervals (RTIs) of 10-13 days, for a total of 0.99 or 1.07 lb ai/A. Applications were made using ground equipment at volumes of 60-77 gal/A, and included the use of a non-ionic surfactant at 0.1% v/v. Single control and duplicate treated samples of plums were harvested from each field trial 7 days after treatment (DAT). Samples were stored frozen for up to 6 months prior to extraction for analysis, an interval supported by the available storage stability data. The number and geographical representation of the submitted field trials adequately addresses the conditional data request.

The liquid chromatography with tandem mass spectrometry (LC/MS/MS) method (Method GRM 02.25) used for determining residues of methoxyfenozide in/on plums was adequately validated in conjunction with the analysis of field trial samples. For this method, methoxyfenozide residues are extracted with acidic methanol, diluted and purified using solid phase extraction (SPE), and then analyzed by LC/MS/MS. The validated limit of quantitation (LOQ) is 0.020 ppm and the limit of detection (LOD) is 0.006 ppm.

Following the last of four broadcast foliar applications of methoxyfenozide (FlC) totaling 0.99-1.07 lb ai/A, residues of methoxyfenozide were 0.14-0.50 ppm in/on 4 samples of plums harvested at 7 DAT. Average residues were 0.31 ppm and the highest average field trial (HAFT) residues were 0.43 ppm.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the plum field trial data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 322948.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. All aspects of this study were conducted in accordance with the requirements for GLP, with the exception of data collected for weather, irrigation, test site history, maintenance chemical application and soil property. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Methoxyfenozide is a diacylhydrazine insecticide used on a variety of crops for control of armyworms and other lepidopterous pest species. Methoxyfenozide mimics the action of the molting hormone of lepidopterous larvae, causing the larvae to undergo an incomplete and premature molt, which ultimately results in their death. Methoxyfenozide is currently registered to Dow AgroSciences. Permanent tolerances are established for methoxyfenozide *per se* on a wide variety of plant commodities at levels ranging from 0.05 ppm in/on field corn grain and sweet corn ears to 160 ppm in/on soybean aspirated grain fractions [40 CFR §180.544(a)(1)].

As a condition of registration for use on stone fruits, the Agency required an additional two field trial on plums in EPA growing Regions 10 and 11 (DP# D274516, M. Nelson, 08/AUG/2002). Dow AgroSciences has submitted the current plum field trials in response to this requirement. The nomenclature and physicochemical properties of methoxyfenozide are presented below in Tables A.1 and A.2.

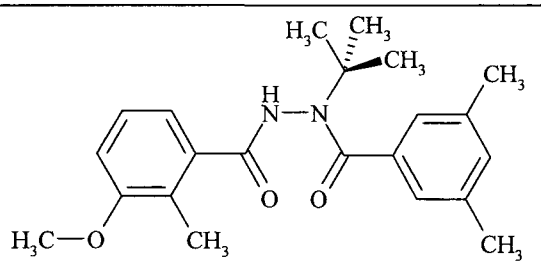
Table A.1. Methoxyfenozide Nomenclature.	
Chemical structure	
Common name	Methoxyfenozide
Company experimental name	RH-2485
IUPAC name	N-*tert*-butyl-N′-(3-methoxy-*o*-toluoyl)-3,5-xylohydrazide
CAS name	3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide
CAS registry number	161050-58-4

Table A.1. Methoxyfenozide Nomenclature.	
End-use product (EP)	2 lb/gal FlC (Intrepid ® 2F; EPA Reg., No 62719-442)

Table A.2. Physicochemical Properties of Methoxyfenozide.		
Parameter	Value	Reference
Melting point/range	206.1-208°C	DP# 231303, H. Podall, 19/MAY/1997
pH	7.0	
Density	0.740 ± 0.0081 g.cm^3	
Water solubility (mg/L at 20°C)	3.3	
Solvent solubility (g/L at 20°C)	N-heptane 1.87 Xylene 3.38 1,2-dichloroethane 36.72 Methanol 192.92 2-Propanol 50.22	
Vapor pressure at 25°C	1.33 x 10^{-5} Pa	
Dissociation constant, pK_a	None	
Octanol/water partition coefficient, $Log(K_{OW})$	3.72 ± 0.04	
UV/visible absorption spectrum	No absorption expected at λ> 300 nm	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Two plum field trials were conducted in EPA growing Regions 10 and 11 during 2004 (Tables B.1.1 and B.1.2). In each field trial, methoxyfenozide (2 lb/gal FlC) was applied to plum trees as four broadcast foliar applications during fruit development at rates of 0.61-0.67 lb ai/A/application, for a total of 2.46-2.66 lb ai/A. Retreatment intervals were 10-13 days, and applications were made using ground equipment at volumes of 60-77 gal/A, and included the use of a non-ionic surfactant.

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (City, State; Year)	Soil characteristics[1]			
	Type	%OM	pH	CEC (meq/g)
Fresno, CA 2004	Loam	NR	NR	NR
Royal City, WA 2004	Sandy Loam	NR	NR	NR

[1]These parameters are optional except in cases where their value affects the use pattern for the chemical.

Detailed climatological data were not provided, but general summaries of weather conditions during the field trials were reported for each site. No usual weather conditions were noted. The tests were conducted according to normal agricultural practices for the regions, and information was provided on the maintenance pesticides and fertilizers used at each site.

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TABLE B.1.2. Study Use Pattern.

Location (City, State; Year) Trial ID	End-use product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Single Rate (lb ai/A)	RTI [1] (days)	Total Rate (lb ai/A)	
Fresno, CA 2004 PL1	2 lb/gal FlC	Four broadcast foliar applications during fruit development (BBCH 78-87)	75-77	0.266-0.271	10-12	1.07	Agridex 0.1%
Royal City, WA 2004 PL2	2 lb/gal FlC	Four broadcast foliar applications during fruit development (BBCH 75-79)	60	0..247-0.251	10-13	0.99	Agridex 0.1%

[1] RTI = Retreatment Interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones [1]	Plum	
	Submitted	Requested[1]
		U.S.
1	--	--
2	--	--
3	--	--
4	--	--
5	--	1
6	--	--
7	--	--
8	--	--
9	--	--
10	1	5
11	1	1
12	--	1
13	--	--
Total	2	8

[1] Requested field trials for an individual tolerance. For this submission, the two submitted field trials adequately address the conditional data request (DP# D274516, M. Nelson, 08/AUG/2002).

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of plums (≥5 lb/sample, ~24 plums) were harvested from each test at 7 DAT. Samples were placed within frozen storage within 4 hours of harvest, stored frozen at the field sites for 6-22 days, and then shipped frozen to Dow AgroSciences, Indianapolis. Samples were frozen with liquid nitrogen and ground, then stored at <-20°C at the analytical laboratory until analysis.

B.3. Analytical Methodology

Samples of plums were analyzed for residues of methoxyfenozide using an LC/MS/MS method, "Determination of Residue of Methoxyfenozide in High Moisture Crops by Liquid Chromatography with Tandem Mass Spectrometry Detection" (GRM 02.25). This method has

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been previously reviewed in conjunction with a petition for use on soybeans (DP# 316528, W. Cutchin, 25/APR/2006), and has also been used for analysis of methoxyfenozide in blueberries and peanuts.

For this method, residues were extracted with methanol:0.1N HCl (90:10, v/v) and centrifuged. An aliquot of the supernatant was then diluted with water, and residues were purified using a Phenomenex Strata 96-well SPE plate. The SPE plate was washed with a 60% water:methanol:formic acid (60:40:0.1, v/v/v), and residues were eluted with acetonitrile. The eluate was evaporated to dryness, and the residues were reconstituted in water:acetonitrile (70:30), containing 0.1% formic acid. The samples were then analyzed by LC/MS/MS using external standards and monitoring the m/z 369→313 transition. The validated LOQ for plums is of 0.02 ppm and the LOD is 0.006 ppm.

The above method was validated in conjunction with the analysis of field trial samples, using control samples of plums fortified with methoxyfenozide at 0.02-1.0 ppm. The method is adequate for data collection.

C. RESULTS AND DISCUSSION

The LC/MS/MS method (Method GRM 02.25) used for determining residues of methoxyfenozide in/on plums was adequately validated in conjunction with the analysis of field trial samples. The average method recovery from samples fortified at 0.02-1.0 ppm was 90%, with a standard deviation of 6%. Apparent residues of methoxyfenozide were <LOD in/on all control samples. Adequate sample calculations and example chromatograms were provided, and the fortification levels used for the concurrent recoveries bracketed the anticipated residue levels.

Samples were stored frozen for up to ~6 months prior to extraction for analysis (Table C.2). Adequate storage stability data are available indicating methoxyfenozide is stable under frozen conditions for up to 7.5 months in grapes. These data support the storage intervals and conditions incurred by the field trial samples.

Following four broadcast foliar applications of methoxyfenozide (FlC) totaling 0.99-1.07 lb ai/A, residues of methoxyfenozide were 0.14-0.50 ppm in/on 4 samples of plums harvested at 7 DAT (Table C.3). Average residues were 0.31 ppm and the HAFT residues were 0.43 ppm (Table C.4).

Common cultural practices were used to maintain plants, and the weather conditions and maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Concurrent Recoveries of Methoxyfenozide from plums.				
Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean ± Std. Dev. (%)
Plums	0.02	6	82, 82, 88, 82, 84, 87	84 ± 3
	0.2	2	94, 92	93 ± 1
	1.0	5	96, 95, 94, 93, 95	95 ± 1
	Total	**13**	**82-96**	**90 ± 6**

TABLE C.2. Summary of Storage Conditions.			
Matrix	Storage Temperature (°C)	Actual Storage Duration (months) [1]	Interval of Demonstrated Storage Stability (months) [2]
Plum	-20	5.1-5.8	12

[1] Duration from harvest to extraction.
[2] DP# 269986, M. Nelson, 07/AUG/2002.

TABLE C.3. Residue Data from Plum Field Trials with Methoxyfenozide (FlC).						
Trial ID (City, State; Year)	EPA growing Region	Variety	Total Rate (lb ai/A)	PHI (days)	Residues (ppm) [1]	
Fresno, CA 2004 PL1	10	French prune	1.07	7	0.23	0.14 [2]
Royal City, WA 2004 PL2	11	Frier	0.99	7	0.35	0.50

[1] The LOQ and LOD are 0.02 ppm and 0.006 ppm, respectively.
[2] Average of duplicate analyses.

TABLE C.4. Summary of Residue Data from Plum Field Trials with Methoxyfenozide (FlC).									
Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm) [1]						
			n	Min.	Max.	HAFT [2]	Median	Mean	Std. Dev.
Plums	0.99-1.07	7	4	0.14	0.50	0.43	0.29	0.31	0.16

[1] The validated LOQ is 0.02 ppm.
[2] HAFT = Highest Average Field Trial.

D. CONCLUSION

The plum field trial data are adequate and support the use of methoxyfenozide (FlC) on plums as up to four foliar applications during fruit development at up to 0.25 lb ai/A/application, for a maximum of 1.0 lb ai/A/season. The data support a minimum RTI of 10 days and a PHI of 7 days.

E. REFERENCES

DP#: 269986

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Subject:	PP# 1F06213. Methoxyfenozide in/on Field Corn and Sweet Corn; Poultry Tolerances; and Higher Tolerances on Other Selected Animal Commodities. Risdue Chemistry Review.
From:	M. Nelson
To:	D. Davis
Dated:	07/AUG/2002
MRIDs:	45213500, 45213502 through 45213514

DP#:	274516
Subject:	PP# 1F06259. Methoxyfenozide in/on Stone Fruits and Prunes. Residue Chemistry Summary Document.
From:	M. Nelson
To:	M. Laws/J. Tavano
Dated:	07/AUG/2002
MRIDs:	45313302, 45313303, 45313304

DP#:	316528
Subject:	Methoxyfenozide. Use on Soybeans. Summary of Analytical Chemistry and Residue Data. Petition Number 3F6794
From:	W. Cutchin
To:	W. Cutchin.
Dated:	25/APR/2006
MRIDs:	46153802

F. DOCUMENT TRACKING

RDI: DNR (07/APR/2009); WC (27/APR/2009)
Petition Numbers: 1F06259
DP#: 322948
PC Code: 121207

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R171134

Chemical Name: Methoxyfenozide

PC Code: 121027
HED File Code:
Memo Date: 6/2/2009
File ID: 00000000
Accession #: 000-00-0130

HED Records Reference Center
6/19/2009